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Prebreathe Protocol for Extravehicular Activity Technical Consultation Report

Prepared by

Mike Duncan

NESC Human Space Flight Operations Super Problem Resolution Team (SPRT) Lead

July 2005

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1.0 Authorization and Notification

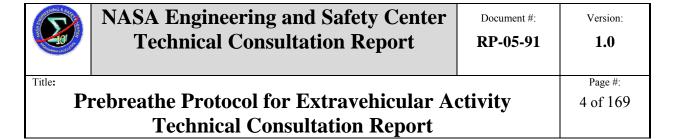
The request to conduct a technical consultation was initiated by Mr. Philip Engelauf, NASA Johnson Space Center (JSC), on May 12, 2005.

Mr. Ralph Roe, Director of the NASA Engineering and Safety Center (NESC) authorized a Consultation Report be prepared in an out-of-board action by the NESC Review Board (NRB) on May 26, 2005.

The consultation Plan was developed by Mr. Jerry Ross, NESC Chief Astronaut, and approved by the NRB on June 2, 2005.

At the request of the NESC, the independent peer review Team convened on June 29, 2005 to conduct a review of the Decompression Sickness (DCS) risks associated with the Extra Vehicular Activity (EVA) Campout Prebreathe (PB) protocol for its consideration for use on future missions.

The final report was submitted on July 8, 2005 and approved by the NRB on July 28, 2005.



2.0 Signature Page

Mike Duncan, Lead (non-voting)	7/22/2005 Date
J. D. Pork, Deputy Dead (non-voting)	8/10/05
Jerry Ross, NESC Chief Astronaut (non-voting)	27 Juc 2005
John Herrington, Safety and Mission Assurance (non-voting)	7/25/05 Date
Carolin Etife MG	7/27/05 Date
Richard Moon	JULY 22, 2005
Keith Van Meter	7/27/05 Date
Bruce Butler	Hizlor Date
Day Sheffeld	27 July 05-
Charles Contant X	18 Aug 2005

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3.0 List of Team Members, Ex Officio Members, and Others

Team Members

Mike Duncan, Lead (non-voting)

J. D. Polk, Deputy Lead (non-voting)

Jerry Ross, NESC Chief Astronaut (non-voting)

John Herrington, Astronaut, Safety and Mission Assurance (non-voting)

Caroline Fife

Richard Moon

Keith Van Meter

Bruce Butler

Paul Sheffield

Charles Contant, Jr.

Presenters

John Curry

Mike Gernhardt

Laura Moore

Joe Dervay

Johnny Conkin

Dan Fitzpatrick

Attendees

Beth Moses

John Raines

Jennifer Clevenger

John McCullough

Joe Tanner

Whitney Maples

Keith Brandt

Mike Bloomfield

Craig Stencil

Mike Powell

James Waligora

Smith Johnston

Heide Stefanyshyn-Piper

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4.0 Executive Summary

In the performance of EVA by that National Aeronautics and Space Administration (NASA) astronauts, there exists a risk of DCS as the suit pressure is reduced to 4.3 pounds per square inch, absolute (psia) from the International Space Station (ISS) pressure of 14.7 psia. Several DCS-preventive procedures have been developed and implemented. Each of these procedures involve the use of oxygen (O₂) prebreathe to effectively washout tissue nitrogen (N₂). One of these procedures, the Campout PB protocol, has existed for many years as a possible method for N₂ reduction prior to EVA, but has never been used on-orbit. There is limited ground-based testing to validate in comparison to the Exercise PB Protocol currently used on the ISS. It is based, however, on the 10.2 psia protocol that has been successfully used for most of the EVAs performed from the Space Shuttle airlock. Because the Campout protocol has some day-of-EVA time saving advantages, and a low predicted DCS risk, some future ISS assembly crews and flight control teams would like to have the option of using it nominally (routinely) prior to EVA. The management of the ISS Programs convened an expert independent review team (herein referred to as the Team) to conduct an independent review of the DCS risks associated with the EVA Campout PB protocol for its consideration for use on future ISS missions.

At the request of the NESC, the peer review Team convened on June 29, 2005. The major findings and recommendations of the expert panel are as follows:

- 1. There is no direct experimental data to confirm the potential DCS risks of the Campout PB protocol. However, based on model data, statistical probability, physiology, and information derived from similar PB protocols, there is no compelling evidence to suggest that the Campout PB protocol is less safe than the other NASA approved PB protocols.
- 2. The Team recommends that Campout PB protocol be accepted for use in "nominal operations".
- 3. The Team agrees that the way in which the PB protocols are listed in the proposed JSC Flight Rule represents an ordering, in decreasing rank of pedigree based on the reliability of experimental data, and recommends that this ordering be retained, in order that imperatives favoring Campout can be appropriately balanced against potential risks.
- 4. The Team recommends that the order of the last two sentences of the proposed flight rule regarding Campout be reversed and modified into a single sentence so that the final portion of the flight rule reads:
 - "3. Campout PB Protocol Rationale: Model predictions and similarity to the Shuttle 10.2 psia staged-protocol show this to be an acceptable protocol, but with some increased risk, and greater uncertainty, compared to the Exercise PB Protocol. This protocol was designed to be more conservative (as analytically determined) than the currently published shuttle 10.2 psia prebreathe protocol, although it has no direct laboratory testing, suited vacuum chamber or direct on-orbit experience. (Ref. A13-103, EVA Prebreathe Protocol)."

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5.0 Consultation Plan

A Charter established the ISS Campout EVA PB Protocol Review within the NESC. It defined the mission, responsibilities, membership, and conduct of operations for this consultation. This consultation was initiated out-of-board by the authority of the NESC Director, Ralph Roe. NESC provides independent oversight for the Agency as part of the Human Space Flight Operations SPRT. The objective of this consultation was to review the physiological, modeling and operations data related to ISS Campout PB Protocol DCS risk and to assess the appropriateness of the proposed JSC flight rules regarding the use of the Campout PB protocol. Specific questions were posed to the review Team in the Charge, with the findings and recommendations to be documented in a written report and out-briefed to the NRB and identified stakeholders.

The initiator was Mr. Phil Engelauf, Deputy Chief, Flight Director Office. Dr. Mike Duncan is the Human Space Flight Operations SPRT Lead (non-voting). Dr. J.D. Polk is the Deputy Lead (non-voting). Dr. Caroline Fife from the University of Texas Health Science Center, Houston was tasked with assembling the independent voting members of the Team, identified in Section 3.0. The Lead and Deputy Lead identified the critical areas of information necessary for the Team briefing, and assembled the presenters. Informational materials were circulated to the voting and non-voting members prior to the meeting date.

Presentations were made during a convened meeting on June 29, 2005, at the Center for Advanced Space Studies in Houston, Texas, to educate the review Team about the background of PB protocol development, physiology of altitude DCS, statistical methods for development and analysis such as modeling, the specific details of the various PB protocols, and some aspects of operations which are pertinent to this review (e.g., available equipment, physical limitations, anticipated numbers of EVA, CUFF protocols, etc.). Presenters included Dr. Mike Duncan who presented the Charge; Mr. John Curry, Flight Directors Perspective; Ms. Laura Moore, Campout Operational Drivers; Dr. Mike Gernhardt, PB Protocol Development; Dr. Joe Dervay, Campout Details; Dr. Johnny Conkin, Modeling Methods; and Dr. Dan Fitzpatrick and Dr. Dervay, Discussion of the draft Flight Rule. After the Charge was reviewed by Dr. Duncan, the Team was allowed to deliberate privately with the input of the non-voting members, Drs. Polk and Duncan, under the supervision of Mr. Jerry Ross, NESC Chief Astronaut. The EVA Integrated Product Team (IPT) presenters remained available during Team deliberations to answer the questions which arose.

Analysis Techniques Used

The Team consisted of six voting members (B. Butler, C. Contant, C. Fife, P. Sheffield, R. Moon, and K. Van Meter), and two non-voting members (M. Duncan and J. Polk). The process was observed by Mr. Ross from the SPRT and Mr. John Herrington (astronaut) representing S&MA. Following the modeling data presentations, PB protocol information, and other

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pertinent information, the Team deliberated for approximately four hours. It was determined that further data analysis by Drs. Gernhardt and Conkin would be useful to help the Team determine the DCS risk of Campout (see "Summary of Modeling Results using the test results of Phase IV as the basis for extrapolation to the ISS Campout protocol," in Section 6.3 and Appendix B). The results of this analysis were e-mailed to the Team. Deliberations continued via two telephone conference calls held on July 1 and 4, 2005. Dr. Gernhardt answered further questions regarding modeling calculations during the July 4th conference call of the voting members. After questions of all members were answered, Dr. Gernhardt left the call and the Team continued its deliberations. After extensive, detailed discussion, the Team unanimously agreed on its recommendations. A draft report prepared by Dr. Fife was circulated via e-mail on July 4, 2005. Between July 4 and 8, 2005, revisions were offered by the Team members and collated by Dr. Fife. Drs. Duncan and Polk and Mr. Ross reviewed the report with regard to the accuracy of the background information and the NASA procedural details. The final report was submitted to the NRB for approval on July 8, 2005.

The analysis performed by Drs. Conkin and Gernhardt are detailed in the appended documents. To estimate the DCS risk of the Campout PB, standard calculations utilizing a published model were used to create an "effective R-value" for N₂ elimination from tissues based on a 360-minute tissue tension. An inert gas kinetic model was then utilized to take into account the overnight PB. Finally, a published logistic regression model was utilized to account for the microgravity simulation. The limitations of this method are discussed briefly in Section 6.3, and provided in detail in Appendix C. The Team reviewed this data with Dr. Gernhardt via phone after reviewing his written report. Other data regarding modeling was presented to the Team by Drs. Conkin and Gernhardt during the June 29, 2005 meeting and handouts from these presentations are also attached. Dr. Contant from the review Team offered further general information regarding the use of modeling in other areas of medicine and physiology to provide a context for these techniques.

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6.0 Description of the Problem, Proposed Solutions, and Risk Assessment

6.1 Problem

The current Campout PB protocol does not have specific ground-based testing to determine its DCS risk and therefore, safety, for use as a nominal PB procedure for the ISS EVA. It has been designated as acceptable based on its similarity to the 10.2 psia staged PB protocol used successfully for the Space Shuttle EVAs. An independent safety assessment was requested. The following is an analysis of factors contributing to this problem, the analysis of the data, and the proposed solutions.

Stakeholders

There were four stakeholder groups represented by the individuals present at the review Team meeting. The viewpoints of each group are summarized as follows:

1. The Astronaut Viewpoint:

The astronauts who spoke at the meeting perceive certain benefits to having Campout PB available as a nominal procedure. Their position indicates that Campout PB:

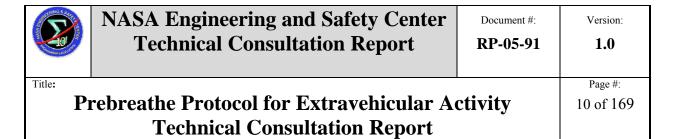
- a. Would simplify PB when the mission parameters are particularly demanding, complex, or time-consuming, especially when back-to-back EVAs are scheduled.
- b. Would provide a further option for PB if contingencies arise.
- c. Would have day-of-EVA time saving advantages.
- d. Discussion should focus on "acceptable risk" rather than a direct comparison of DCS risk between, for example, the Exercise Protocol and Campout Protocol.

2. The Flight Controllers and Directors Viewpoint:

- a. The Flight Director's perspective is that many EVAs have been performed on the Space Shuttle utilizing the 10.2 psia staged decompression protocol, all without problems.
- b. Campout PB would provide potentially significant operational advantages to specific upcoming missions, for example, missions which may require back-to-back EVAs by reducing the total hours in the "work day".

3. Medical Operations Viewpoint:

a. Primary interest is in safety of all aspects of operations.



4. **NESC Viewpoint:**

- a. Primary goal is assessment of and recommendations for mission safety.
- b. Agree that operational considerations are a component of the evaluation process

6.2 Factors Contributing to the Problem

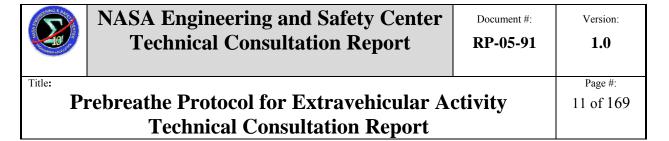
Unique Physiology

DCS is a risk which is inherent to significant altitude exposure. With significant decompression exposures of any kind, the risk of DCS can never be reduced to zero. Unlike compressed air diving, with altitude decompression, the fractions of DCS that are serious (neurological or "Type II") is less than 4 percent even on exposures with high decompression stress, with the vast majority of altitude DCS cases presenting as "Type I" or "pain only". The critical methodological difference in altitude exposures (compared to diving operations) is that, as a result of PB, a large fraction of body N₂ is eliminated *prior to* decompression. This has significant protective effects on well-perfused tissues such as the brain and spinal cord, thus conferring a protective effect from serious DCS. However, resting (non-exercise) PB reaches diminishing returns in the reduction of "pain only" DCS since these symptoms arise from gas phase in relatively poorly perfused or "slow" tissues such as tendon and muscle. Taken as a whole, NASA PB tests on humans (including rejected protocols) resulted in a DCS incidence of approximately 18 percent, almost all of which were "pain only". In subjects demonstrating Central Nervous System symptoms, five out of six subjects developing Type II DCS did so with protocols in which there was no O₂ PB, confirming the protective effect of PB on these critical tissues. Another variable is that the risk of DCS increases with the duration of EVA, so that even a relatively high-risk protocol might be tolerated if the EVA is very short.

It is recognized that even if DCS were to develop during EVA, it would likely be Type I (pain only), not impact EVA success, and respond completely to O₂ on return to the ISS. Unlike diving DCS, greater than 98 percent of altitude symptoms resolve with two hours of ground level O₂ only. Data pooled from many sources suggest that if the PB protocol has an incidence of less than 15 percent TOTAL DCS, then the likelihood of *serious* DCS may be immeasurably low. However, unlike diving, altitude DCS occurs *while the astronaut is performing EVA* and thus could affect crew safety and mission performance.

The Evolution of PB Testing Methods

The evolution of the various PB protocols at NASA reflects the progression of decompression research from the 1970's to the present. The following approaches have been and continue to be used:



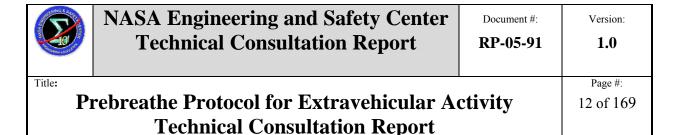
- 1. Ground-based testing of specific PB periods (with increasing sophistication in the simulation of microgravity).
- 2. Mathematical modeling based on accumulated data from closely related studies.
- 3. Multi-center prospective trials to evaluate specific PB techniques (e.g. "Exercise PB") designed with operational considerations in mind and with carefully defined *a priori* accept/reject criteria.

For example, Dr. James Waligora tested many PB protocols (3, 3.5, 4 hours) in which the DCS incidence ranged from 20-36 percent. Exercise simulated the arm movement of the crank on the Shuttle payload doors and other Shuttle contingency tasks. In testing the four-hour "In-suit" PB protocol and the one-hour 10.2 psia "staged decompression," specific "R" values were identified for acceptable tissue tensions, and "reject" criteria were identified ("Grade 3 DCS, any Type II, pain limiting performance, etc."). In the 10.2 psia staged decompression PB ground-based tests, a DCS incidence of 23 percent was observed. To date, there have been 143 EVAs using protocols based on this R value with no reported cases of DCS during EVA.

In the late 1990's, the EVA requirements for ISS necessitated PB protocols which were more time efficient. Other operational disadvantages of the 10.2 psia staged decompression for ISS included the necessity of isolating the EVA crew overnight, O₂ mask time, logistics, high O₂ use, risk of elevated O₂ levels in the ISS due to mask leak, the untested nature of the relatively "short" overnight depressurization compared with the Shuttle experience, and the unknown effect of sleep on off-gassing. These issues drove the development of the "Exercise PB" protocol. The long range goals of this project were not limited to PB development alone and included:

- 1. The testing and implementation of a two-hour PB protocol for EVA from ISS by 1999.
- 2. Transforming "the EVA culture" to more of a "diving environment" mentality with:
 - a. A clear DCS disposition policy (thus eliminating disincentives to reporting symptoms).
 - b. Improved DCS treatment protocols.
 - c. Defining "Acceptable DCS risk," a concept well entrenched in the diving community.

Research which enabled this program to proceed included the recognition that ground-based microgravity simulation (no ambulation or adynamia) was an important experimental variable, and the discovery that exercise significantly enhances N_2 off-gassing (e.g.10 minutes exercise at 75 percent oxygen intake (VO₂) peak during a one hour PB protocol was equivalent to four-hour resting O₂ PB). However, studies had to be done to define whether vigorous exercise might counteract the effect of microgravity. The initial part of the five-year research program was to establish a definition for "acceptable DCS risk", which had not been determined up to that time.



The long range concept has always been to develop a "family" of PB protocols which would allow flexibility similar to that used in diving. The definition of "acceptable risk" involved identifying on-orbit DCS treatment capability, the development of a "cuff checklist" (attached to the cuff of the arm during EVA which specifies a sequence of actions in the event of symptoms), and contingency planning.

Acceptable risk in PB protocol development was ultimately defined by the following parameters:

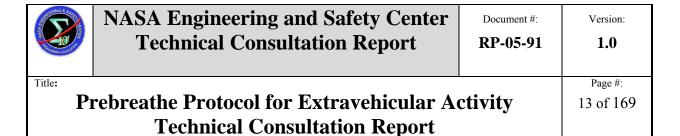
The highest DCS risk consistent with a 95 percent probability that two of three members would always be available for EVA was 21 percent, and that during testing, DCS and grade IV venous gas emboli (VGE) incidence would be below the threshold for any reported case of Type II DCS.

Acceptable DCS risk was further reduced to account for possible delay to re-pressurization, long-term health risks and other factors. Subsequently, the first multi-center trial was developed with peer review of the research trial design. The criteria established in testing protocols for ISS were NOT applied to the Shuttle PB protocols. The limit for this trial was a DCS incidence of less than 15 percent at 95 percent Confidence Limit (CL), and Grade 4 VGE less than or equal to 20 percent at 95 percent CL. These limits were more conservative than any previous EVA PB trial. It is noted in retrospect that the 10.2 psia staged PB was accepted at a higher rate of DCS in ground-based testing than would be accepted if the studies were done today to current requirements (e.g. adynamia).

There are numerous factors which result in an "operational safety margin":

- 1. Crews never do less than the required PB time (tasks often take longer than expected to complete).
- 2. Physical activity of orbiting crew members are higher than resting subjects in ground-based tests which further enhances N₂ elimination.
- 3. Increased activity of tasks, such as moving hoses are not accounted for in trials or models.
- 4. Suit purge increases time of PB.

It is important to note the difference in DCS incidence between ground-based trials and EVA experience. The incidence of DCS in Shuttle ground-based trials was 22.8 percent (8/35) with 0/143 incidence during EVA. The difference between the incidence of DCS observed in Shuttle ground-based trials and the zero incidence during EVA may be accounted for by a number of factors: possible reduction in bubble "micronuclei" due to microgravity, the prolonged time of depressurization, and the long time of O₂ purge in the suit. Analysis of the 95 percent Bayesian CLs for the risk differences suggest that the Shuttle ground simulation over estimates the DCS



risk in EVA, while ISS ground EVA simulation provide an accurate prediction of DCS risk (it is possible that the risk of DCS in ISS ground-based trials and EVA are the same). The better correlation between ISS ground-based trials and predicted DCS risk during EVA may be due to better ground-based trial design.

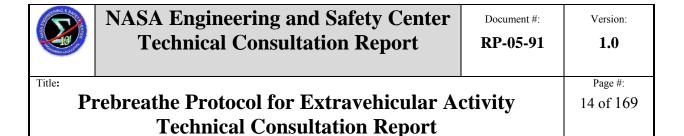
Modeling Data

The modeling techniques used to assist in the development of the PB protocols are well known in medicine and physiology having been used to develop, for example, the cardiac risk score from the Framingham Study data, as well as in pharmaceutical trials, the techniques of which are accepted by the Food and Drug Administration. It is important to note that, utilizing modeling techniques, the risk of DCS is almost the same for all the PB protocols (including Campout PB), and the confidence intervals overlap. There is a tendency to rank the risks within "acceptable risks" even when the differences are small. Given the overlapping confidence intervals, it may be impossible to detect a real difference in risk between the PB protocols, based on modeling.

The Development of the ISS Campout PB Protocol

The Space Shuttle 10.2 psia staged PB protocol was accepted in 1982 based on 35 tests at JSC with a 23 percent DCS incidence (all Type I). Post *Challenger*, this PB was amended to improve N₂ washout by either extending the stay at 10.2 psia from 12 to 24 hours, or increasing the final O₂ PB from 40 to 75 minutes. There was no direct testing of the protocol after these changes, but based on model analysis, the risk of DCS was estimated at approximately 24 percent with a 5 percent risk of EVA termination. In 1991, an option was added to allow the deletion of the first hour of mask PB when the stay at 10.2 psia was longer than 36 hours. This option was accepted based on analysis and expert consultation, without direct testing, and has a highly successful record, with no cases of DCS.

In 1995, the Campout PB protocol was developed which required a 60-minute initial PB prior to mask doffing at 10.2 psia, a 10-hour air lock stay at 10.2 psia, a minimum of 60 minutes of O₂ via mask during the waste management break at 14.7 psia, and a minimum of 60 minutes of additional O₂ via mask at 10.2 psia prior to suit donning, followed by 30 minutes of final in-suit PB. The protocol was approved by similarity to the Shuttle 10.2 psia protocol. Approval was concurred by Medical Operations and the Space and Life Sciences Directorate. The approval memorandum recognized that these procedures were still in development and anticipated the possibility of further conservative trades of time at 10.2 psia for additional O₂ time on the mask. In 1999, there were some changes in the protocol due to a slower airlock depress time than anticipated. The result was an increase of 20 minutes in the total O₂ time on the mask, and a decrease in the time at 10.2 psia by 1 hour and 20 minutes. These changes were approved by the Bioastronautics EVA IPT and forwarded to the Office of Space Medicine for concurrence.



There are precedents for using modeling to create PB protocols in the absence of ground-based testing. There have been "one off" missions during the Shuttle-MIR program which required special PB protocols and models to account for stack pressures greater than the normal 10.2 psia staged protocol. These protocols were developed with conservative assumptions and used in flight operations without direct ground-based tests. The highly successful 10.2 psia procedure used in Shuttle was altered from its original based on modeling to increase its safety factor. It is also important to note that while there has been no specific ground-based testing of Campout PB, Phase IV of the Exercise PB study was a 2-hour PB with 95 minutes of light exercise, and a 30 minute suit donning period at 10.2 psia and 26.5 percent O₂. This ground-based test of Phase IV is nearly identical to the day-of-EVA Campout PB procedure, which has the same amount of O₂ PB, and the same or slightly more metabolic activity during O₂ PB. For this reason, Phase IV could be considered ground-based data similar to that of Campout PB. The Phase IV ground trials resulted in 14 percent DCS in 57 subjects. Whereas the results did not quite meet the DCS accept criteria for ISS EVAs, they were lower than the ground tests of the Shuttle 10.2 psia staged protocol. Additionally, the Campout PB protocol has an extra hour of O₂ PB, and 8 hours and 40 minutes overnight campout at 10.2 psia.

While similar, the Campout PB for ISS differs from the 10.2 psia staged PB used on the Shuttle in the following ways:

- 1. Campout PB has shorter time at 10.2 psia, i.e., 8.0 hours for sleep compared to the 12.0 hour minimum required for the Shuttle (13.5 hours is the shortest duration experienced at 10.2 psia with Shuttle, with 40.0 hours being the average).
- 2. The mask time for Campout PB has been increased from 1 hour to 2 hours and 10 minutes to compensate for the decreased time at 10.2 psia.
- 3. On ISS, 60 percent of the time at 10.2 psia is spent sleeping (compared to 30 percent in Shuttle), with an anticipated subsequent decrease in metabolic rate, the effects of which are not known.

An important point is that the 10.2 psia staged PB protocol is the best available procedure for the Space Shuttle EVA, and the Campout PB was designed to be "analytically more conservative," even though there is no ground-based testing for validation.

Issues Relating to the Flight Rule

For nominal EVAs (*nominal* is defined as routine, scheduled EVA), there are currently four PB protocols certified for use, of which three may be used on ISS:

- 1. 10.2 psia staged PB (used only for Space Shuttle EVAs).
- 2. 4-hour "In-suit" PB (Shuttle or ISS).

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- 3. Cycle Ergometer with Vibration Isolation System (CEVIS) Exercise PB (only ISS due to equipment requirements).
- 4. ISS Campout PB (ISS).

A protocol exists for "contingency" EVA (EVAs required to effect the safety of vehicle and crew). One of the above PB protocols would be used if time allows. If time does not allow, a minimum of 2.5 hours of unbroken PB with greater than 95 percent O₂ is recommended at a vehicle pressure less than 12.5 psia. It is estimated that this would reduce the risk of incapacitating DCS to less than 50 percent for an EVA of up to six hours in duration. Contingency EVA requires consultation with the Flight Surgeon.

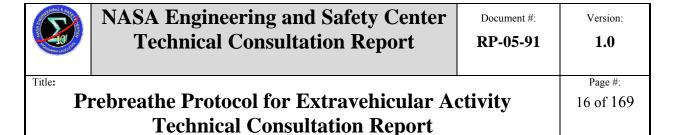
The final proposed version of the flight rule was achieved on April 14, 2004, through consensus of the Bioastronautics EVA IPT, representatives of the Flight Directors Office, Astronaut Office, and EVA Office. There was concurrence by the Medical Operations, the Space Medicine Configuration Control Board, and the Director, Space and Life Sciences.

Final Version, endorsed at MEDOPS meeting (April 14, 2004)
"THE EXERCISE PREBREATHE (PB) PROTOCOL, 4 HOUR IN-SUIT
PROTOCOL, AND CAMPOUT PB PROTOCOL, ARE ALL
ACCEPTABLE FOR USE ON ISS WITH VARYING DEGREES OF DCS
RISK UNCERTAINTY. THE SELECTION OF A PB PROTOCOL FOR
A GIVEN EVA WILL DEPEND ON THE INTEGRATED MISSION
OBJECTIVES, DECOMPRESSION SICKNESS (DCS) RISK, CREW
TIMELINE, AND OVERALL OPERATIONAL RISKS.

The PB protocol selected for a given EVA event should consider all the factors affecting risk to the crew and mission. Predicted risk of DCS, procedural risk due to timeline complexity or fatigue, and criticality of completing the EVA tasks within a specified timeframe are all factors that must be weighed.

The PB protocols are ranked according to their pedigree based on laboratory testing, on-orbit and suited vacuum chamber experience, and model predictions.

- 1. Exercise PB Protocol Rationale: The Exercise PB protocol meets the current DCS acceptance criteria, is the most rigorously laboratory tested, and the protocol with the lowest predicted risk of DCS. (This acceptable risk was defined in the NASA DCS Risk Definition & Contingency Plan, 1998, (total DCS < 15 percent at 95 percent Confidence Limit (CL), < 20 percent Grade 4 VGE at 95 percent CL, No Type II (Serious) DCS).
- 2. 4 hr In-Suit PB Protocol Rationale: The 4 Hr In-suit PB protocol has been extensively used on ground suited vacuum chamber exposures (>300 exposures), with acceptable DCS risk (<1.5 percent total DCS observed, no Type II). However, it has not undergone the same level of laboratory testing as the Exercise PB.
- 3. Campout PB Protocol Rationale: Model predictions and similarity to the Shuttle 10.2 psi staged-protocol show this to be an acceptable protocol, but with some increased risk, and greater uncertainty, compared to the Exercise PB Protocol. There is no direct laboratory testing, suited vacuum chamber, or direct on-orbit experience with the



Campout protocol. However, this protocol was designed to be more conservative (as analytically determined) than the currently published shuttle 10.2 prebreathe protocol. (Ref. A13-103, EVA Prebreathe Protocol)".

Choice of PB Protocol

As currently proposed, the JSC Flight Rule is structured to recommend "CEVIS" (Exercise PB) since the amount of ground-based testing on which it is established is the most comprehensive of all the protocols. However, the Flight Director is given the option of choosing other PB protocols. When making a decision about which PB protocol to use, the Mission Operations Directorate considers crew safety (i.e., DCS prevention, fatigue, day length), supply of consumables (O₂, Carbon Dioxide (CO₂) scrubbing), and operations (timeline, length of EVA, protocol complexity, mission objectives, urgency of EVA). It is anticipated that Campout PB would not be the first choice of most crews due to the long mask time and the logistical problems associated with overnight isolation. Since the benefit of Campout PB is lost if the depressurization is not begun on time, the crew still has the option of performing the Exercise PB.

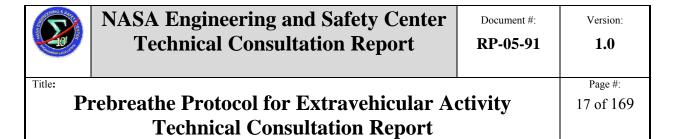
For most EVAs, the Exercise PB is likely to be the one most commonly used. However, in recent ISS history, since the loss of *Columbia*, there are frequently only two crew members on the ISS. Under these conditions, if EVA is necessary, the four-hour PB is currently designated as the PB protocol of choice because it is less complex to perform with limited crew. Therefore, there is a precedent for choosing a PB protocol other than Exercise PB, based on operational considerations. In addition, there are up to 21 potential single point failures with either the CEVIS, the PB hose assembly, or the 10.2 psia depress infrastructure that could result in the need for an alternative protocol.

The proposed flight rule is written to imply an ordering of PB protocols, in descending order with regard to pedigree (based on laboratory testing, on-orbit and suited vacuum chamber experience, and model predictions) as follows:

- 1. Exercise PB
- 2. In-suit PB
- 3. Campout PB

General Comments by the Team

- 1. The Team wishes to emphasize that the risk of DCS cannot be reduced to zero, irrespective of the decompression PB protocol.
- 2. It is likely that given a sufficient number of EVAs, DCS will be observed. This will not mean that the PB protocol has failed. The observance of DCS during EVA will allow an



actual incidence to be determined for the PB protocol, and further refinement can be done if needed

- 3. Prediction of DCS probability in space is a "rare event process". As a result, calculation of an actual risk for EVA cannot be done until there is a case of DCS during EVA, and many EVAs may be performed before that occurs. Until that time, all DCS risk calculations are extrapolations from available data.
- 4. Modeling is a well-accepted method of studying complex processes such as DCS, and the review Team is comfortable accepting modeling data.
- 5. Despite the fact that the Team is comfortable with modeling, the Team wishes to emphasize that it would be unwise to absolute rank a PB protocol *without* specific ground-based testing above those protocols where such data exist.
- 6. The Team recognizes that there is some degree of uncertainty (the risk of "not knowing") as a result of not having ground-based data that exactly simulate the Campout PB protocol.

6.3 Proposed Solutions

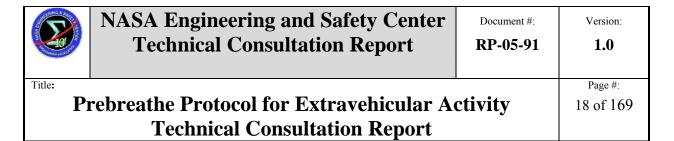
The review Team requested Dr. Gernhardt use the Exercise PB Phase IV data and model an eight-hour 10.2 psia pre-exposure to provide the Team with further information on the relative risk of DCS with Campout PB. The results of this analysis follow.

Summary of Modeling Results using the Test Results of Exercise PB Phase IV as the Basis for Extrapolation to the ISS Campout PB Protocol

The Phase IV ground test had 57 non-ambulatory subjects who performed an 80-minute O_2 PB, spent 30 minutes at 10.2 psia/26.5 percent O_2 , repressed to 14.7 psia on 100 percent O_2 and performed an additional 40 minutes of O_2 PB. During this time, they performed 95 minutes of light activity at 5.8 ml/kg-min O_2 consumption. Total O_2 PB time was 120 minutes.

For Campout PB, on the day-of-EVA, starting with the 70-minute hygiene break, the astronauts will perform 70 minutes of O₂ breathing and 30-60 minutes at 10.2 psia/26.5 percent O₂. After donning the suits, they will repress to 14.7 psia on 100 percent O₂ and perform 50 minutes of insuit 100 percent O₂ PB. The similarities of the Campout PB procedure to "Phase IV" are:

- 1. Astronauts perform exactly the same light activity tasks that were modeled in Phase IV (airlock prep, donning the biomed and liquid cooling garment, donning the lower torso assembly).
- 2. Astronauts will have an equal 120 minutes of O₂ PB (70 minutes before the depress versus 80 minutes for Phase IV, and 50 minutes in the suit versus 40 minutes for Phase IV).



3. Astronauts will perform the same 95 minutes of light activity, plus some additional light activity at some uncharacterized rate (between 3.6-5.8 ml/kg-min).

Differences are:

- 1. Astronauts perform some additional light activity during their translation to and from the waste management compartment.
- 2. Astronauts will spend a slightly longer time at 10.2 psia (approximately 60 versus 30 minutes for Phase IV).

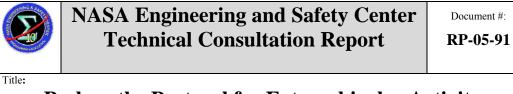
These differences should, if anything, result in increased N₂ off-gassing for the Campout PB, compared to the ground-based tests of Phase IV.

Model Extrapolations and Risk Assessment

In Phase IV there were 8/57 subjects with DCS (14 percent). The model approach was to calculate the equivalent Tissue Ratio (TR) based on a 14 percent DCS incidence associated with the NASA ground database of resting PB in subjects who ambulated and performed EVA simulation exercise at altitude. A range of equivalent R-values were calculated based on the relationship between the probability of DCS in this subject group and the TR in the 360-minute halftime tissue (Historical TR curve), and based on the following assumptions:

- 1. *Most conservative* assumed that the "true" decompression stress from Phase IV would be the upper 95 percent confidence level of the observations of 14 percent DCS in 57 subjects. That would result in 23.9 percent DCS. The 23.9 percent DCS was reflected onto the historical TR curve, to select an effective R-value for the Phase IV exposure.
- 2. *Moderately Conservative* assumed that the "true risk" of Phase IV was 14 percent DCS, but then selected the upper 95 percent CL from the historical TR curve.
- 3. Least Conservative used the 14 percent risk from Phase IV as the true risk, and combined that with the best estimate of the historical TR curve to develop the least conservative value of the effective R-value associated with the Phase IV test.

The effective R-values derived were then reduced based on the standard exponential inert gas exchange model — accounting for the additional one-hour O_2 PB the night before, and the eight hours and 40 minutes exposure at 10.2 psia/26.5 percent O_2 . These tissue tensions were then run through the logistic regression model that includes the micro-gravity simulation. The resulting best estimate predictions of DCS range from 6.1 to 7.4 percent with the 95 percent confidence interval from 2.9 to 14.3 percent. This falls within the DCS accept limit of DCS less than or equal to 15 percent at 95 percent CLs.



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Limitations of this Approach

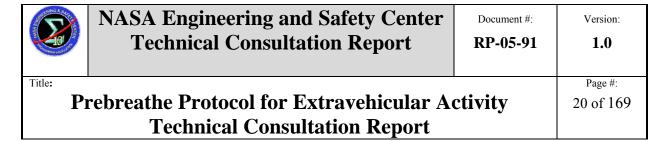
There are numerous limitations to this approach, including combining several different models. Additionally, this approach causes calculations to be done "backwards", beginning with the Phase IV exposure and then adding the one-hour of O_2 PB and the overnight campout. This conservative approach would have the effect of negating the advantage of the 10.2 psia overnight Campout, as the theoretical tissue tensions would be equivalent or less than the N_2 partial pressure at 10.2 psia. On-orbit, the order of exposure would be reversed.

To summarize, since a conventional R-value does not apply due to the fact that N₂ elimination is being enhanced by increased metabolic activity, an effective R-value must be created. This is a standard mathematical calculation utilizing a published model. Then, to take into account the PB from the night before, the 360-minute tissue tension was adjusted with a standard inert gas kinetic model. Lastly, a published logistic regression model was utilized to account for the microgravity simulation. The final result predicts a slightly higher risk than a simple logistic regression of the Campout PB protocol alone. This slight increase in calculated risk is likely due to a number of factors including: the "reverse order" of the way the conditions were presented in the calculations, and the fact that the Exercise PB Phase IV ended with a cluster of several cases of DCS which caused the trial to be stopped. Since DCS incidents fluctuate during a trial, the true risk might have been lower if the trial had continued. Further possible protective effects of the Campout PB, when compared to Phase IV, are the repressurizations to 14.7 psia for the hygiene break and the suit O₂ breathing. During ground-based trials, which did NOT involve PB prior to the depress to 10.2 psia, there was an almost immediate onset of VGE on depressing from 10.2 psia to 4.7 psia. This suggests that there was some gas phase that had occurred at 10.2 psia which may have allowed bubble growth on further depress in the absence of O₂ PB. However, with Campout PB, there is the possible protective effect of two repressurizations which may resolve any gas phase having developed from the 10.2 psia depress.

Answers to the "Charge":

1. Is the ISS EVA Campout PB protocol acceptable for use in nominal operations?

The Team considered the available ground testing data, modeling, and the similarity/applicability to the Shuttle 10.2 psia protocol with its associated ground validation, modeling, and flight experience. Additional modeling data provided by Dr. Gernhardt was reviewed. It is the opinion of the Team that Campout PB can be used for nominal operations. The proposed flight rule is written to imply an ordering of PB protocols, in descending order with regard to pedigree. The listing of the PB protocols in the JSC Flight Rule should be maintained to provide an ordered preference so that DCS risk considerations can be balanced against other operational considerations.



2. If the answer to the question in #1 is no, then is there a set of limited or restricted circumstances or off-nominal operations where the EVA Campout prebreathe protocol would be considered acceptable? In these circumstances, balancing risk across all ISS operations, including timeline, would need to be considered by the flight control team in deciding when to use the EVA Campout PB protocol.

See answer #1 above.

- 3. If the answer to the question in #1 is yes, then is it of equal risk when compared to the exercise that the PB protocol or the four-hour in-suit PB protocol?
 - The Team considered the available ground testing data, modeling, and flight experience of the various PB protocols. The Team is not able to determine the **actual DCS risk** of Campout PB due to the lack of either ground-based trials or on-orbit data. Extrapolations from Exercise PB Phase IV data using modeling suggest that the risk of DCS with Campout PB is no greater than the four-hour PB. Campout PB has slightly greater risk and uncertainty than the Exercise PB, although the DCS risk predictions are still within acceptable limits based on model extrapolations.
- 4. If the answer to the question in #3 is no, then is the proposed flight rule an acceptable approach to aide the selection between the available PB protocols and balancing the risk of overall operations?

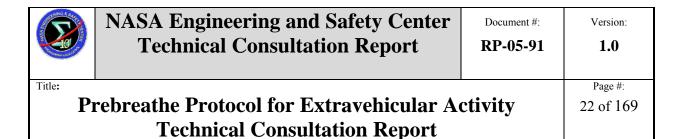
Yes. See the final recommendations in Section 8.2.

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7.0 Data Analysis

Information contained in the following documents was reviewed, either at the June 29, 2005 meeting, or during subsequent conference calls with the Team.

- 1. "Acceptability of Campout Prebreathe Protocol for ISS EVA Operations," Joe Dervay, MD.
- 2. "Overview of Shuttle and ISS Exercise Prebreathe Protocols and ISS protocol Accept/Reject Limits," Mike Gernhardt, PhD.
- 3. "Notes and Analysis of NASA Shuttle and ISS Prebreathe Options with Special Reference to 'Campout' Prebreathe," Johnny Conkin, PhD (03/18/05).
- 4. "Summary of Modeling Results Using the Test Results of Phase IV as the Basis for Extrapolation to the ISS Campout Protocol," Mike Gernhardt, PhD.
- 5. Data from Ground-Based Trials, Modeling, and EVAs from Shuttle and ISS were carefully reviewed by the Team.



8.0 Findings, Root Causes, Observations, and Recommendations

8.1 Findings

- **F-1.** There is no experimental evidence to confirm the modeling predictions regarding DCS using the Campout PB protocol. Based on model data, statistical probability, physiology, and information derived from similar PB protocols, it is reasonable to believe that the Campout PB protocol poses no greater risk than any other accepted PB protocol. There is a greater degree of uncertainty with regard to Campout because the probability of DCS has been estimated using modeling.
- **F-2.** The way in which the PB protocols are listed in the proposed flight rule implies an ordering, in decreasing order of pedigree based on the reliability of experimental data, and recommends that this ordering be retained.
- **F-3**. All currently accepted PB protocols have significant disadvantages:
 - a. All are relatively complex and require complicated infrastructure with many possible point failures.
 - b. No matter which PB protocol is chosen, even if all were known to be equally safe, each has a different set of advantages and disadvantages in actual use.
- **F-4.** The development of PB protocols has evolved over time:
 - a. "Accept/Reject" criteria used for new protocols are stricter than criteria applied in the past.
 - b. Modeling provides useful information regarding PB protocol development but cannot replace human ground-based trials.

8.2 Recommendations

- **R-1.** The Campout PB protocol should be accepted for use in "nominal operations".
- R-2. The final sentence of the proposed flight rule pertaining to Campout PB protocol, which currently reads: "... this protocol was designed to be more conservative (as analytically determined) than the currently published shuttle 10.2 psia prebreathe protocol." should be changed to state, "... this protocol was designed to be more conservative (as analytically determined) than the currently published shuttle 10.2 psia prebreathe protocol, although it has no direct laboratory testing, suited vacuum chamber or direct on-orbit experience."
- **R-3.** Continued research in PB protocol development is necessary, for the purpose of increasing safety as well as simplicity.
- **R-4.** Future PB protocols should be created based on prospective, operationally relevant ground-based trials, rather than on model data or similarity to prior PB protocols.

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9.0 Lessons Learned

- 1. All currently accepted PB protocols have significant disadvantages:
 - a. All are relatively complex and require complicated infrastructure with many possible point failures.
 - b. No matter which PB protocol is chosen, even if all were known to be equally safe, each has a different set of advantages and disadvantages in actual use.
- 2. The development of PB protocols has evolved over time:
 - a. "Accept/Reject" criteria used for new protocols are stricter than criteria applied in the past.
 - b. Modeling provides useful information regarding PB protocol development but cannot replace human ground-based trials.
- 3. Continued research in PB protocol development is necessary, for the purpose of increasing safety as well as simplicity
- 4. Future PB protocols should be created based on prospective, operationally relevant ground-based trials, rather than on model data or similarity to prior PB protocols.

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10.0 Definition of Terms

Adynamia Immobility, usually refers to studies in which the subjects are not allowed

to ambulate in order to simulate microgravity

Corrective Actions Changes to design processes, work instructions, workmanship practices,

training, inspections, tests, procedures, specifications, drawings, tools, equipment, facilities, resources, or material that result in preventing, minimizing, or limiting the potential for recurrence of a problem.

Depress Reduce pressure.

Finding A conclusion based on facts established during the assessment/inspection

by the investigating authority.

Lessons Learned Knowledge or understanding gained by experience. The experience may

be positive, as in a successful test or mission, or negative, as in a mishap or failure. A lesson must be significant in that it has real or assumed impact on operations; valid in that it is factually and technically correct; and applicable in that it identifies a specific design, process, or decision that reduces or limits the potential for failures and mishaps, or reinforces a

positive result.

Nominal Scheduled, routine.

Observation A factor, event, or circumstance identified during the

assessment/inspection that did not contribute to the problem, but if left uncorrected has the potential to cause a mishap, injury, or increase the

severity should a mishap occur.

Problem The subject of the independent technical assessment/inspection.

Recommendation An action identified by the assessment/inspection team to correct a root

cause or deficiency identified during the investigation. The recommendations may be used by the responsible C/P/P/O in the

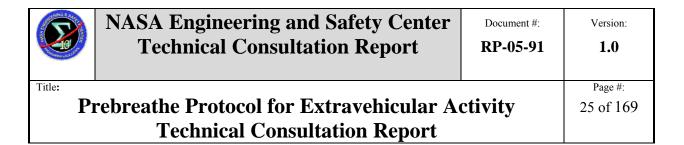
preparation of a corrective action plan.

Root Cause Along a chain of events leading to a mishap or close call, the first causal

action or failure to act that could have been controlled systemically either

by policy/practice/procedure or individual adherence to

policy/practice/procedure.



Type I Pain only DCS.

Type II Serious or neurological DCS.

Brief Description of PB Protocols:

10.2 psia Staged PB Requires 60 minutes of O₂ breathing the day prior to EVA; followed by a

minimum of 12 hours at 10.2 psia; and completed with in-suit O₂ breathing

for 40-75 minutes.

4-Hour In-suit PB Requires O₂ breathing for four hours in the space suit before EVA.

Exercise PB (CEVIS) Requires 1 hour 20 minute O₂ breathing by mask while performing a

specified exercise regimen, 20-minute depress at 10.2 psia for suit

donning, and one-hour of O₂ in-suit before EVA.

ISS Campout PB Requires one-hour of O₂ before depress to 10.2 psia for overnight stay

(minimum of 8 hours 40 minutes), with O₂ by mask during hygiene break after repress to 14.7 psia for 1 hour 10 minutes, then depress back to 10.2

psia with 50 minute O₂ breathing in-suit before EVA.

11.0 Minority Report

There were no dissenting opinions on this consultation. Team Recommendations were unanimous.

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VOLUME II: APPENDICES

- A. NESC ITA/I Request Form
- B. "Summary of Modeling Results Using the Test Results of Phase IV as the Basis for Extrapolation to the ISS Campout Protocol"
- C. "Notes and Analysis of NASA Shuttle and ISS Prebreathe Options with Special Reference to 'Campout' Prebreathe"
- D. "Acceptability of Campout Prebreathe Protocol for ISS EVA Operations"
- E. "Overview of Shuttle and ISS Exercise Prebreathe Protocols and ISS protocol Accept/Reject Limits"
- F. EVA Camp-Out Prebreathe Protocol Peer Review Team Charge
- G. "Estimated Risk of DCS and VGE in ISS Campout Prebreathe"
- H. "EVA Prebreathe Protocol Comparison: Operational Drivers"
- I. List of Acronyms

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Appendix A. NESC ITA/I Request Form



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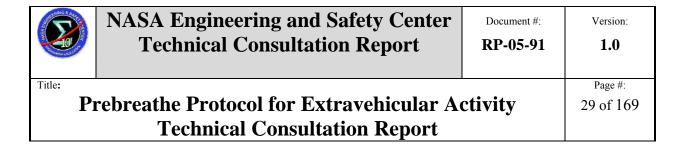
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NASA Engin	eering and Safety Cen	ter
F	Request Form	
Submit this ITA/I Request, with associated artifa NRB Executive Secretary, M/S 105, NASA		
Section 1: NESC Review Board (NRB) Executive Se	ecretary Record of Receipt	
Received (mm/dd/yyyy h:mm am/pm) 12/22/2004 4:40 PM	Status: New	Reference #: 04-093-E
Initiator Name: Bryan O'Connor	E-mail: bryan.oconnor@nasa.gov	Center: HQ
Phone: () , Ext	Mail Stop:	*
Short Title: Cracked Thick Film Coatings on Electron Vehicle	nic Packages on the Delta 2 Lau	nch
Description: Bryan O'Connor requested that the NESO assessments regarding the start and propogation of crepackages on the Delta 2 Launch Vehicle. A FRR is s would like a second opinion to brief the AA with before Source (e.g. email, phone call, posted on web): e-mail	acks associated with thick film on the ackeduled for the 8th of January 8	coatings on electronic
Type of Request: Consultation		
Proposed Need Date:		
Date forwarded to Systems Engineering Office (SEO): (mm/dd/yyyy h:mm am/pm):	
Section 2: Systems Engineering Office Screening). (IIIII 00 JJJJ	
Section 2.1 Potential ITA/I Identification		
Received by SEO: (mm/dd/yyyy h:mm am/pm): 12/2:	3/2004 12:00 AM	
Potential ITA/I candidate? Yes No		
Assigned Initial Evaluator (IE): No initial evaluat	ion. This was approved Out of	Board
Date assigned (mm/dd/yyyy):		
Due date for ITA/I Screening (mm/dd/yyyy):		
Section 2.2 Non-ITA/I Action		
Requires additional NESC action (non-ITA/I)? Ye	s No	
If yes:		
Description of action: Consultation		
Actionee: Ken Cameron 12/23/2005	D-4 01/07/2005	
Is follow-up required? Yes No If yes: D		4 4
Follow-up status/date: Schedule at 6 Jan 2005 1	NRB to present report/recomme	ndations
If no:		
NESC Director Concurrence (signature):		



Section 3: Initial Evaluation						
Received by IE: (mm/dd/yyyy h:mm am/pm):						
Screening complete date:						
Valid ITA/I candidate? Yes No						
Initial Evaluation Report #: NESC-PN-						
Target NRB Review Date:						
Section 4: NRB Review and Disposition of NCE Response Report						
ITA/I Approved: Yes No Date Approved:	Priority: - Select -					
ITA/I Lead: , Phone () - , x						
Section 5: ITA/I Lead Planning, Conduct, and Reporting						
Plan Development Start Date:	·					
ITA/I Plan # NESC-PL-						
Plan Approval Date:						
ITA/I Start Date Planned: Actual:						
ITA/I Completed Date:						
ITA/I Final Report #: NESC-PN-						
ITA/I Briefing Package #: NESC-PN-						
Follow-up Required? Yes No						
Section 6: Follow-up						
Date Findings Briefed to Customer:						
Follow-up Accepted: Yes No						
Follow-up Completed Date:						
Follow-up Report #: NESC-RP-						
Section 7: Disposition and Notification						
Notification type: - Select - Details:						
Date of Notification:						
Final Disposition: - Select -						
Rationale for Disposition:						
Close Out Review Date:						

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Form Approval and Document Revision History

Approved:		
	NESC Director	Date

Version	Description of Revision	Office of Primary Responsibility	Effective Date
1.0	Initial Release	Principal Engineers Office	29 Jan 04

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Appendix B. "Summary of Modeling Results Using the Test Results of Phase IV as the Basis for Extrapolation to the ISS Campout Protocol"

Phase IV Protocol vs. Campout

The phase IV ground test had 57 non ambulatory subjects, who performed a 80 minute 02 prebreathe, spent 30 minutes at 10.2 psi/26.5% 02, repressed to 14.7 psi on 100% 02 and performed an additional 40 minutes of 02 prebreathe. During this time they performed 95 minutes of light activity at 5.8 ml/kg-min 02 consumption. Total prebreathe time was 120 minutes, with 30 minutes at 10.2 psi/26.5% 02, and 95 minutes of the light activity (5.8 ml/kg-min)

For campout, on the day of EVA, starting with the 70 minute hygiene break, the astronauts will perform 70 minutes of 02 breathing, 30-60 minutes at 10.2 psi/26.5% 02, after donning the suits they will repress to 14.7 psi on 100% 02 and perform 50 minutes of in-suit 100% 02 prebreathe. During this time they will perform exactly the same light activity tasks that we modeled in phase IV (airlock prep, donning the biomed and liquid cooling garment, donning the lower torso assembly). They will perform some additional light activity during their translation to and from the waste management compartment.

They will have an equal 120 minutes of 02 prebreathe (70 minutes before the depress vs. 80 minutes for phase IV, and 50 minutes in the suit vs. 40 minutes for phase IV), they will spend slightly longer time at 10.2 psi (~ 60 minutes vs. 30 minutes for phase IV), and perform the same 95 minutes of light activity, plus some additional light activity at some uncharacterized rate (between 3.6-5.8 ml/kg-min).

Model extrapolations

In phase IV there were 8/57 subjects with DCS or 14% DCS. The model approach is then to calculate the equivalent Tissue Ratio (for 14% DCS) associated with our ground database of resting prebreath, ambulatory subjects who ambulated and performed EVA simulation exercise at altitude. Figure one below is the relationship between the probability of DCS in this subject group and the TR in the 360-minute halftime tissue. From the relationship in figure one, we calculated a range of equivalent r-values for the phase IV exposure based on the following assumptions.

1. *Most conservative*-We assumed that the "true" decompression stress from phase IV would be the upper 95% confidence level of the observations of 14% DCS in 57 subjects. That would result in 23.9% DCS. We then combined the 23.9% DCS with the upper 95% confidence limit of the curve in figure one to select an effective R-value for the phase IV exposure.

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- 2. *Moderately Conservative* We assumed that the "true risk" of phase IV was 14% DCS, but then selected the upper 95% confidence limit from the curve on figure one.
- 3. *Least Conservative* We used the 14% risk from phase IV as the true risk, and combined that with the best estimate from figure one, to develop the least conservative value of the effective R-value associated with the phase IV test.

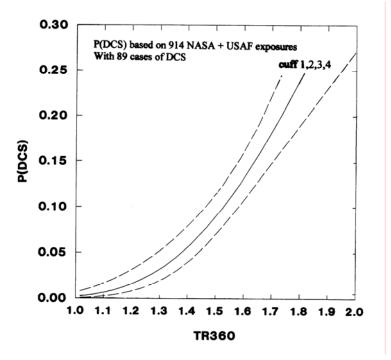


Figure 1. Relationship between P(DCS) and Tissue ratio in the 360-minute half-time tissue in 914 NASA and USAF exposures that included ambulation, resting prebreathe and EVA simulation exercise at altitude.

The effective r-values derived as described above where then lowered based on the standard exponential inert gas exchange model; accounting for the additional one hour O_2 prebreathe the night before, and the 8 hrs and 40 minutes exposure at $10.2 \text{ psi/}26.5\% O_2$. The tissue tensions exercise, where they run through the logistic regression model that includes the micro-gravity simulation, is shown below:



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P(DCS) with adynamia and exercise at 4.3 psia

			==
P(DCS)	LOWER 95% CI	UPPER 95% CI TR360	
0.0074456863481	0.0028951044209	0.019012576235 1.2095152468	
0.009569854824	0.0038539281325	0.023562791164 1.245470814	
0.01229251892	0.0051178163292	0.029229972148 1.2844362926	
0.015777452994	0.0067774153735	0.036292339456 1.3266636481	
0.017558	0.007645	0.039813 1.3457* exercise PB	
0.020230131567	0.008947077518	0.045094670683 1.3724259387	
0.025906358984	0.01176949878	0.056060356327 1.4220190808	
0.0278	0.01268	0.0594 1.4375 campout + 10 min	PB
0.033121398262	0.015420542196	0.069702209306 1.4757637624	
0.037689	0.017765	0.076522 1.507 10.2 psia staged	
0.042258685063	0.0201138959	0.086628787175 1.5340075173	
0.046635	0.022390	0.094575 1.558 4.0-hr in-suit	
0.053776499592	0.02610505336	0.10754085187 1.5971269715	
0.068209976365	0.033693915637	0.13320999454 1.6655302796	
0.086164597666	0.04322510323	0.16442914152 1.7396597633	
0.10829605059	0.055084829546	0.20192436324 1.8199947721	
0.13527054076	0.069692944847	0.24622201923 1.9070547826	
0.16770027207	0.087488565352	0.29747806034 2.0014027582	

^{*} TR360 estimated from separate cuff regression (effective TR)

	estimate	SE	p-value	
B ₀ (constant)	-1.662	0.193	<0.01	
$B_1 [ln(TR360 - 0.78)]$	3.149	0.349	<0.01	
B_2 (LBA)	-1.156	0.400	<0.01 LBA = 1 for adynamic condition, 0 = ambulation	n
B ₃ (EXER)	0.586	0.222	<0.01 EXER = 1 for exercise at altitude, $0 = no exercise$	se at
altitude				

Regression based on 1,401 records but only 76 records were from tests of adynamia.

Other details available in: Conkin J, Powell MR. Lower body adynamia as a factor to reduce the risk of hypobaric decompression sickness. Aviat Space Environ Med 2001; 72:202-14.

The resulting best estimate predictions of DCS range from 6.1- 7.4% with the 95% confidence interval from 2.9 - 14.3 %. This falls with the DCS accept limit of DCS \leq 15% at 95% c.1

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Limitations of this approach

There are numerous limitations to this approach, including combining several different models. Additionally with this approach we had to work backwards, starting with the phase IV exposure first and then adding one the one hour of 02 prebreathe and the overnight campout, after the phase IV exposure. In reality it would be the other way around. This approach was similar to the method that was used to calculate the predicted risk for the exercise prebreathe protocol accounting for the flight factors. For those estimates we assumed the "true risk" of DCS was 6.5% (upper 95% c.1 of 0 DCS/45 subjects). The difference was that the phase IV exposure was then adjusted to a lower tissue tension to account for the initial one hour prebreathe and overnight campout (using our standard exponential inert gas elimination mode). It occurs to me that we might be overstating the effect of micro gravity simulation with this approach. This is because the trial itself had micro gravity simulation and then we used the effective R-value from that trial as an input to the logistic regression model that accounts for micro gravity simulation. I am less concerned about that for the exercise protocol because the observations themselves were well within the accept criteria, and we assumed that the true risk of DCS was 6.5% vs. the observed risk of 0%.

Campout DCS Predictions based on the LLR model of exercise and micro gravity simulation

The exercise/micro gravity logistic regression model incorporates all of the data collected during the exercise prebreathe studies (table one).

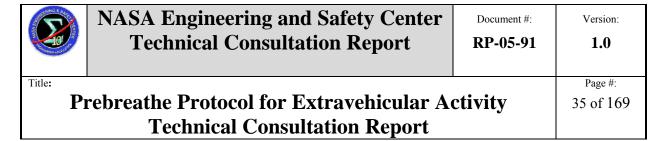


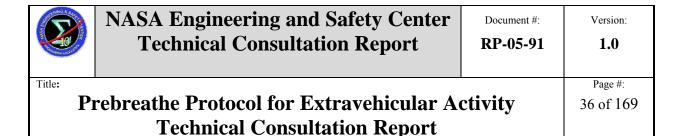
Table 1. Prebreathe Reduction Program Summary

Prot	tocol	Site ¹	Expos	sures Com	pleted		DCS			C	uff		M	ax D	opple	er VG	ΈE
			Males	Females	Total	Ambig.	Type I	Type II	1	2	3	4	0	I	II	III	IV
PRP-	I	D	18	8	26	0	5	0	4	1	0	0	10	10	2	3	1
		Н	15	6	21	0	4	0	2	2	0	0	14	2	1	3	1
	_	C	0	0	0												
	Totals		33	14	47	0	9	0	6	3	0	0	24	12	3	6	2
PRP-	II	D	12	4	16	0	0	0	0	0	0	0	11	3	1	1	0
		Н	16	6	22	1	0	0	1	0	0	0	18	0	1	3	0
	_	С	7	0	7	0	0	0	0	0	0	0	2	1	0	1	3
	Totals		35	10	45	1	0	0	1	0	0	0	31	4	2	5	3
PRP-	III	D	7	2	9	0	1	1	2	0	0	1	7	0	1	0	1
		Н	1	0	1	0	0	0	0	0	0	0	1	0	0	0	0
		C	0	0	0												
	Totals		8	2	10	0	1	1	2	0	0	1	8	0	1	0	1
PRP-	IV	D	15	3	18	0	0	0	0	0	0	0	12	5	1	0	0
		Н	13	5	18	1	4	0	2	3	0	0	13	0	1	4	0
		C	17	4	21	2	4	0	1	3	0	0	9	1	0	4	7
	Totals		45	12	57	3	8	0	3	6	0	0	34	6	2	8	7
PRP-	V-1	D	7	3	10	1	3	0	2	2	0	0	4	0	3	1	2
		Н	0	0	0												
		C	0	0	0												
	Totals		7	3	10	1	3	0	2	2	0	0	4	0	3	1	2
PRP-	V-2	D	1 ²	2	3^2	0	0	1	0	0	0	1	0	0	1	0	2
		Н	0	0	0												
		C	0	0	0												
	Totals		1	2	3	0	0	1	0	0	0	1	0	0	1	0	2
PRP-	V-3	D	23^{3}	5	28^3	0	3	0	0	3	0	0	12	3	4	7	2
		Н	0	0	0												
		C	15	5	20	0	4	0	1	4	0	0	11	1	0	5	3
	Totals		38	10	48	0	7	0	1	7	0	0	23	4	4	12	5

¹ D = Duke; H = Hermann; C = DRDC

² A second male (fourth subject) participated in V-2 but had an incomplete study when the trial was ended prematurely to manage symptoms of the other subject. He had Grade 1 VGE at trial end (after 2h: 33min at altitude).

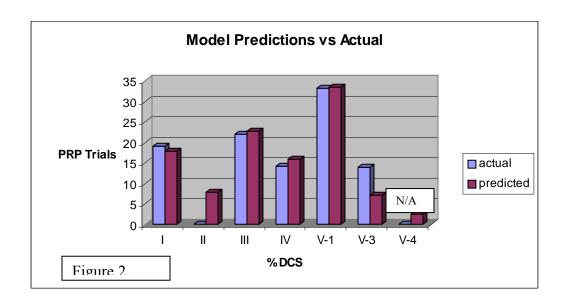
³ A male and female subject were excluded due to protocol deviations during prebreathe.



Direct measurements of 02 consumption as function of time were made for all of the exercises performed on these protocols. The rate constant in the exponential tissue compartment:

$$P1N_2 = P_0 + (P_a - P_0) * (1 - exp - k_i * t)$$

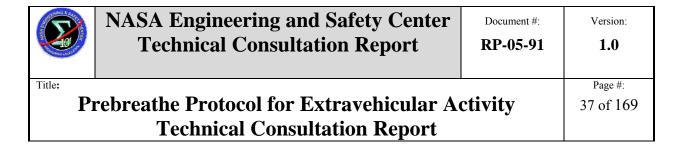
 K_i is then fit to the 02 consumption (mL*kg⁻¹*min⁻¹) using maximum likelihood. (There is a detailed draft report available on these methods). The model provides a significant prediction and goodness of fit of all of the data in phases 1-V-3 as shown below in figure 2.



Likelihood ratio test for improvement: Log likelihood null model = 61.3 Log likelihood NASAEXLR2= $54.6\,$ p value = $.001\,$ (p< .05 is significant) ** One-Sample $\chi 2$ Goodness of fit Test = 6.61 with 4 degrees of freedom and p = 0.842 (significance > .05)

** Hosmer-Lemshow Goodness of fit statistic = 2.188 with 5 degrees of freedom, p = 0.82 (significance > .05)

The following is a breakdown of the campout metabolic profile:



EVENT	TIME	MET (ml/kg/min)
Initial 100% O2 PB	60 min	5.8
10.2 psia at 7.5 ppN2	520 min	3.2 (based on metabolic measurements
during sleep)		
Potty break on 100% O2	70	5.8
Suit don at 7.5 ppN2	60	5.8
Leak + purge + In-suit PB	67	3.5
Ascent to 4.3 psia	30	3.5

The results of the exercise and micro-gravity LLR model predict a DCS risk of .01% for the campout protocol.

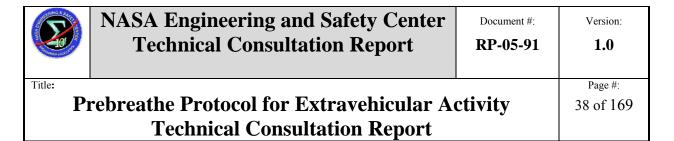
Limitations: This model was developed and calibrated using data from 02 prebreathe durations that ranged from 2-2.5 hrs, and 10.2 psi exposure durations of 0-30 minutes. For this reason it is probably not valid to extrapolate this model to the much longer duration exposures of campout. Additionally it should be noted that this model under predicted the risk of DCS in phase V-4.

Bubble Dynamics Model Predictions:

The Bubble Dynamics Model has been used to develop diving decompression tables that were used in the field with very low DCS incidence. The same model with the same parameterization provided a significant prediction and goodness of fit of the NASA shuttle prebreathe data as shown below.

	DCS	VGE	DCS	VGE	DCS	VGE
Null	-201.46	-306.56				
BGI(480)	-190.94	-208.53	0.0000	0.0000	0.512	0.021
BGI (360) with metabolic gases	-188.78	-272.11	0.0000	0.0000	0.196	0.250

The bubble dynamics model is a mechanistic model of the physics of tissue bubble growth and has been parameterized using independently measured parameters vs. parameterization using statistical optimization techniques. For this reason it has demonstrated the capability of extrapolation across various forms of diving including altitude. The predictions for the Bubble



Growth Index (BGI- instantaneous bubble radius /initial bubble radius) are shown below for: 1). The Ground tests of the shuttle 10.2 psi staged protocol, 2). The ground tests of the 4 hr. 02 prebreathe, 3). A typical "as flown" shuttle protocol with 24 hours at 10.2 psi, and for the proposed ISS campout protocol. The bubble model does not account for micro gravity simulation of any direct effects of exercise. Diving decompression tables based on the bubble dynamics model were developed and used on over 25000 commercial dives, with less than .1% DCS. These tables were designed to control the BGI to less than 3.5.

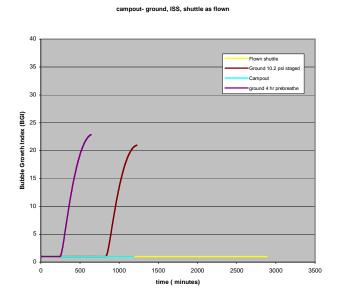
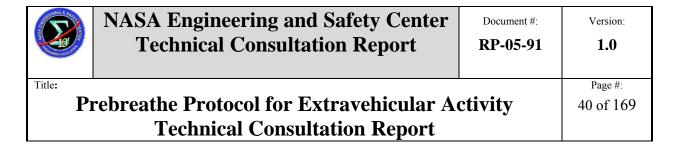


Figure 2. - Theoretical bubble growth associated with ground tests of the 4 hr. prebreathe, the 10.2 psi staged protocol, the proposed ISS campout, and a typical Shuttle protocol with 24 hrs duration at 10.2 psi. The model predicts significant bubble growth associated with the two ground tests, which resulted in approximately 23% DCS, while there is no bubble growth predicted for the as flown shuttle 10.2 psi staged protocol, or the proposed ISS campout.

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Appendix C. "Notes and Analysis of NASA Shuttle and ISS Prebreathe Options with Special Reference to 'Campout' Prebreathe"



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Notes and Analysis of NASA Shuttle and ISS Prebreathe Options with Special Reference to "campout" Prebreathe.

> Johnny Conkin 03 / 18 / 05



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P(Grade IV VGE) for a 40 yo adynamic subject

TR360	P(Grade IV)	(upper 95% CI)	(lower 95% CI)	
1.3	2.881485E-02	0	0	
1.31	3.040683E-02	.1000882	-4.245848E-02	
1.32	3.207076E-02	.1055898	-4.477611E-02	
1.33	3.380901E-02	.1113343	-4.719275E-02	
1.34	3.562397E-02	.1173269	-4.970891E-02	
1.3457	3.782968E-02	.124559	-5.27299E-02	exercise PB
1.36	3.949374E-02	.1300916	-5.505556E-02	
1.37	4.155326E-02	.1368767	-5.788924E-02	
1.38	4.369927E-02	.1439367	-6.083018E-02	
1.39	4.593408E-02	.1512802	-6.388171E-02	
1.4	4.826033E-02	.1589132	-6.704506E-02	
1.41	.0506804	.1668412	-7.032057E-02	
1.42	5.319661E-02	.1750713	-7.371046E-02	
1.43	5.581141E-02	.183609	0772158	
1.4375	5.7848E-02	.1902458	0800238	campout + 10 min PB
1.44	5.852759E-02	.1924582	-8.083536E-02	•
1.45	6.134689E-02	.2016264	-8.457118E-02	
1.46	6.427235E-02	.2111145	-8.842075E-02	
1.47	6.730581E-02	.2209306	-9.238593E-02	
1.48	7.044983E-02	.2310761	-9.646449E-02	
1.49	7.370663E-02	.2415539	1006542	
1.5	7.707816E-02	.2523702	104957	
1.507	7.956183E-02	.26029	1080818	10.2 psia staged
1.52	8.417439E-02	.275019	1138854	
1.53	8.790302E-02	.2868551	1185063	
1.54	9.175456E-02	.2990335	1232275	
1.55	9.573066E-02	.3115536	1280445	
1.558	9.90124	.32184	13196	4.0-hr in-suit
1.56	9.983313E-02	.3244161	1329547	
1.57	.1040634	.3376164	1379501	
1.58	.1084229	.3511546	1430278	
1.59	.1129132	.3650273	1481814	
1.60	.1175351	.3792298	1534034	
1.61	.1222898	.3937571	1586869	
1.62	.1271783	.4086031	1640235	
1.63	.132201	.4237626	1694059	
1.64	.1373585	.439227	1748251	

 $P(Grade\ IV) = 1 - exp\ (-(log(1 + TR360 \ ^7.232 \ ^*(1 + (LBA \ ^*4.951)) \ ^*AGE \ ^1.351 \ ^*(HR \ ^*0.0000342) \ ^1.2246))$



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P(Serious DCS) for 6 hr exposure with exercise at 4.3 psia (only men used from database, and adynamia is not a factor)

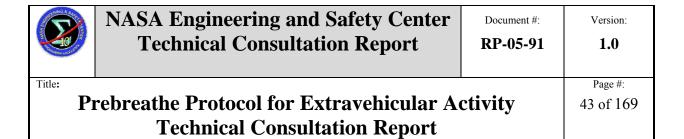
TR180	P(Serious DCS)	(upper 95% CI)	(lower 95% CI)	
1.6279069767	0.008722	0.012628	0.004815	
1.6046511628	0.008205	0.01187	0.0045386	
1.5813953488	0.0077117	0.011147	0.0042743	
1.5581395349	0.00724101	0.0104588	0.00402139	
1.5348837209	0.0067925	0.0098039	0.0037795	
1.511627907	0.0063655	0.00918073	0.003548	
1.4651162791	0.005573	0.0080264	0.0031182	
1.4186046512	0.004858	0.0069865	0.002728	
1.3720930233	0.004215	0.006054	0.002375	
1.3255813953	0.0036395	0.0052209	0.0020572	
1.287	0.003213	0.0046058	0.00182	10.2 psia staged
1.2790697674	0.0031258	0.0044789	0.0017719	
1.2558139535		0.00289	0.0041396	0.0016411
1.2325581395	0.0026694	0.003821	0.0015171	
1.2093023256	0.00246131	0.00352	0.0014	
1.1860465116	0.00226587	0.00324	0.00129	
1.1627906977	0.0020824	0.0029772	0.0011871	
1.1395348837	0.0019106	0.0027303	0.00109	
1.1162790698	0.0017498	0.002499	0.0009993	
1.0930232558	0.001599	0.0022848	0.00091399	
1.0697674419	0.0014594	0.0020839	0.0008345	
1.0465116279	0.0013288	0.0018974	0.0007599	
1.023255814	0.0012074	0.00172389	0.00069069	
1.000000000	0.0010946	0.0015621	0.0006263	
0.9945	0.001068	0.0015249	0.0006114	campout + 10 min
0.97674418605	0.00099015	0.0014133	0.0005666	
0.95348837209		0.0008934	0.001275	0.00051095
0.909	0.0007287	0.0010408	0.0004163	4.0-hr in-suit
0.6976744186	0.0002356	0.0003395	0.00013185	
0.67441860465	0.00020396	0.0002942	0.0001136	
0.6720	0.0002011	0.0002901	0.000112	exercise PB
0.6511627907	0.00017559	0.0002536	9.749e-005	

probability function: risk function model

The particular risk function chosen for the present analysis is:

$$r_i = \chi * \left(\frac{P1N_2}{P2}\right)^{\alpha} * \left[1 + EXER * \epsilon\right] * (t * e^{-\beta t})$$
 Eq. 1

where α , β , χ , and ϵ are unknown parameters to be estimated from data, and P1N₂ (psia), P2 (psia), EXER, and T_{alt} (hrs) are the four variables associated with this four-parameter continuous model. Equation 1 combines both



mechanistic and empirical components. The change in r_i with respect to time is suggested from observations on the rate at which DCS appears. We believe the ratio of $P1N_2$ to P2 to a power α links an evolved volume of gas to the perception of pain better than the ratio alone, and better than the difference in pressure alone. Finally, the contributions from the type, intensity, and duration of exercise while at altitude to the risk of serious DCS are not known. Our simple approach is to estimate a "weight" term ϵ to account for the contribution of any repetitive exercise while at altitude to the risk of serious DCS.

For a test of duration T_{alt} , the integral of r_i with respect to time gives the cumulative risk (r_c) . That is,

$$r_c = \int_0^{T_{ab}} r_i(t)dt$$
 Eq. 2

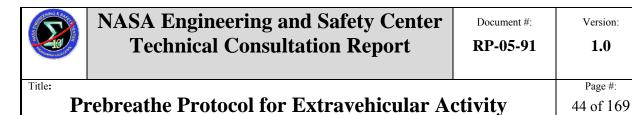
Using r_i given by Eq. 1 in Eq. 2, we obtain the following expression for the estimated cumulative risk:

$$r_{c} = \chi * \left(\frac{\text{P1N}_{2}}{\text{P2}}\right)^{\alpha} * \left[1 + \text{EXER} * \epsilon\right] * \frac{1 - (1 + \beta T_{\text{alt}}) * e^{-\beta T_{\text{alt}}}}{\beta^{2}}$$
Eq. 3

In terms of r_c, the probability of serious DCS sometime before the end of the test is:

$$P(\text{serious DCS}) = 1 - e^{-r_c}$$
 Eq. 4

where e^{-r_c} is P(no serious DCS). Notice that P(serious DCS) is zero if the cumulative risk is zero and approaches one as the risk increases. From Eq. 4, it can be seen that $r_c = -\ln[1 - P(\text{serious DCS})]$, where ln is natural log. Notice that r_c is dimensionless. The derivative of r_c with respect to time is r_i , so $r_i = d(-\ln[1 - P(\text{serious DCS})]) / dt$, or the rate in a finite interval of time at which serious DCS appears in the data set.



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TABLE I. PARAMETER ESTIMATES OF FOUR-PARAMETER MODEL.

Parameter	Estimate	Asymptotic SE	T-ratio	
χ (scale)	0.000613	0.000133	4.60	
β (rate)	1.794	0.219	8.19	
α (power)	4.267	0.142	30.0	
ε (weight)	4.752	0.548	8.67	

SE is standard error, T - ratio is the ratio of the estimate to the SE of the estimate, and an absolute value ≥ 1.96 indicates that the p - value for the estimate is ≤ 0.05 for the test that the true parameter value is zero.

ASYMPTOTIC CORRELATION MATRIX

χ β α 1.000 χ β 0.660 1.000 -0.781 -0.085 1.000 0.408 0.663 -0.121 1.000



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P(DCS) with adynamia and exercise at 4.3 psia

P(DCS)	LOWER 95% CI	UPPER 95% CI	TR360
0.0074456863481	0.0028951044209	0.019012576235	1.2095152468
0.009569854824	0.0038539281325	0.023562791164	1.245470814
0.01229251892	0.0051178163292	0.029229972148	1.2844362926
0.015777452994	0.0067774153735	0.036292339456	1.3266636481
0.017558	0.007645	0.039813	1.3457* exercise PB
0.020230131567	0.008947077518	0.045094670683	1.3724259387
0.025906358984	0.01176949878	0.056060356327	1.4220190808
0.0278	0.01268	0.0594	1.4375 campout + 10 min PI
0.033121398262	0.015420542196	0.069702209306	1.4757637624
0.037689	0.017765	0.076522	1.507 10.2 psia staged
0.042258685063	0.0201138959	0.086628787175	1.5340075173
0.046635	0.022390	0.094575	1.558 4.0-hr in-suit
0.053776499592	0.02610505336	0.10754085187	1.5971269715
0.068209976365	0.033693915637	0.13320999454	1.6655302796
0.086164597666	0.04322510323	0.16442914152	1.7396597633
0.10829605059	0.055084829546	0.20192436324	1.8199947721
0.13527054076	0.069692944847	0.24622201923	1.9070547826
0.16770027207	0.087488565352	0.29747806034	2.0014027582

^{*} TR360 estimated from separate cuff regression (effective TR)

$$\exp(-1.662 + \ln(TR360 - 0.78) * 3.149 - (1.156 * LBA) + (0.586 * EXER))$$

$$P(DCS) = \frac{1}{1 + \exp(-1.662 + \ln(TR360 - 0.78) * 3.149 - (1.156 * LBA) + (0.586 * EXER)]}$$

	estimate	SE	p-value
B ₀ (constant)	-1.662	0.193	<0.01
B ₁ [ln(TR360 - 0.78)]	3.149	0.349	<0.01
B_2 (LBA)	-1.156	0.400	<0.01 LBA = 1 for adynamic condition, 0 =
ambulation B ₃ (EXER)	0.586	0.222	<0.01 EXER = 1 for exercise at altitude, 0 = no
exercise at altitude			

Regression based on 1,401 records but only 76 records were from tests of adynamia

Other details available in: Conkin J, Powell MR. Lower body adynamia as a factor to reduce the risk of hypobaric decompression sickness. Aviat Space Environ Med 2001; 72:202-14.

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Campout Prebreathe Protocol as Proposed 08/16/04

	PN2 360	PN2 180
1. 30 min 02 prebreathe		
2. 31 min O2- depress from 14.7 to 10.2 psi	10.3148	9.1720
3. 8.0 hrs and 40 minutes at 10.2 psi / 26.5% 02	8.5345	7.7258
4. 10 minute repress to 14.7 psia on O2 prebreathe		
5. 30 minute hygiene break while still on O2 prebrea	athe	
6. 31 min 02 - depress to 10.2 psia	7.4442	5.8780
7. 60 min suit donning at 10.2 psia while on 26.5%	O2 7.4503	6.2126
8. 17 min purge and leak check		
9. 40 mins-02 in-suit prebreathe	6.6761	4.9885
10. 10 min additional in-suit prebreathe		
11. 30 min depress to 4.3 psia on body	6.1812	4.2763
	TR360 = 1.4375	TR180 = 0.9945



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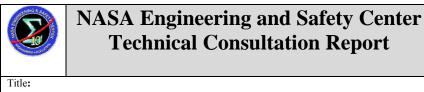
10.2 psia Staged Prebreathe Protocol as Flown (EVA3618.sys)

COMPUTED DECOMPRESSION STRESS FOR 149 EVAs FROM THE SHUTTLE (1984 – 2002)

Astronauts in space suits pressurized to 4.3 psia have not reported decompression sickness (DCS), but research subjects have reported about 20%. One explanation is that operational denitrogenation procedures are conservative, plus other factors in microgravity may reduce the risk of DCS. We computed the tissue ratio (TR), an index of decompression stress for 143 staged prebreathe (PB) protocols from the shuttle and 6 in-suit PB protocols. TR is P1N2 / P2, where P1N2 is calculated N2 pressure in a compartment with a 360 minute half-time for N2 pressure just prior to a space walk (also called Extravehicular Activity or EVA), and P2 is 4.3 psia. The staged protocol incorporates denitrogenation that occurs because the ambient pressure is reduced from 14.7 to 10.2 psia and the O2 concentration in the air is increased to 26.5%. There are also periods of 100% O2 prebreathe from a mask prior to and after the staged decompression while in the space suit. The in-suit PB is simply breathing 100% O2 for 3.5 to 4.0 hrs in the suit at 14.7 psia. The mean TR \pm standard deviation for 149 PBs is 1.511 \pm 0.069 compared to 1.52 ± 0.26 for 245 research subjects at Johnson Space Center with 18.3% DCS. The table shows the decrease in TR during subsequent EVAs since multiple EVAs in the staged protocol are typically done during a shuttle mission, and the results from the in-suit PB protocols.

10.2 psia staged PB	1st EVA	2nd EVA	3ed EVA	4th EVA
mean TR360 ± SD	1.527 ± 0.046	1.480 ± 0.077	1.488 ± 0.083	1.379 ±
number of EVAs	80	47	15	1
in-suit PB				
mean TR360 ± SD	1.600 ± 0.083			
number of EVAs	6			

Astronauts perform conservative PBs in an operational environment since DCS is to be avoided. Adaptation to microgravity may improve denitrogenation. Astronauts are active during PBs, which accelerates N2 washout. Inactivity of the lower body in microgravity before and during



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EVA reduces the risk of Type I DCS in the lower body (1). If fitness is linked to DCS, then astronauts as a group may be less susceptible to DCS than subjects of comparable age.

1. Conkin J, Powell MR. Lower body adynamia as a factor to reduce the risk of hypobaric decompression sickness. Aviat. Space Environ. Med. 2001; 72:202-14.

The same prebreathe information above was evaluated using a 180 minute half-time compartment. The mean TR \pm standard deviation for 149 PBs is 1.274 \pm 0.110.

10.2 psia staged PB	1st EVA	2nd EVA	3ed EVA	4th EVA
mean TR180 ± SD	1.275 ± 0.0087	1.310 ± 0.067	1.282 ± 0.141	1.318 ±
number of EVAs	80	47	15	1
in-suit PB				
mean TR180 ± SD	0.960 ± 0.099			
number of EVAs	6			

	PN2 360	PN2 180
1. n = 143 10.2 psia staged protocols as flown	6.4801	5.5341
	TR360 = 1.507	TR180 = 1.287
2. n = 4 4-hr in-suit protocols as flown	6.6994	3.9087
2	TR360 = 1.558	TR180 = 0.909

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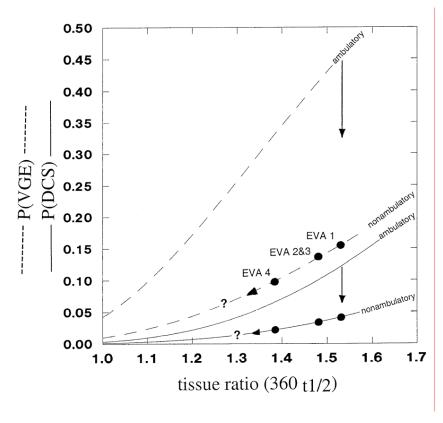


Figure 1. The probability of DCS [P(DCS)] and probability of VGE [P(VGE)] decrease as tissue ratio decreases and decreases if adynamia is included in the estimate of risk.



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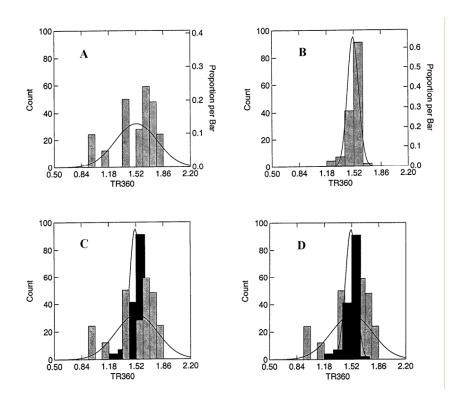


Figure 2. Histograms showing the distribution of TR360 in the 245 records from testing subjects in altitude chambers at JSC (Panel A) and 145 records of astronauts that performed EVAs from the space shuttle (Panel B). Four additional staged decompression records were recovered, but not included in Panel B. A normal density function is imposed on each histogram to provide a visual reference to each mean TR360 (peak of curves) and the variability about each mean (spread of curves). The means are very similar, about 1.51, but the standard deviation is four times smaller in the EVA data (0.07) compared to the chamber data (0.26). Panel C shows the EVA data (dark bars) behind the chamber data (light bars), and Panel D shows the EVA data in front of the chamber data.

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Exercise Prebreathe Protocol as Flown

PN2 360 PN2 180

1. 10 min of dual-cycle ergometery at 75%

of VO2 pk for last 7 min.

2. 24 min of intermittent exercise starting

55 min into PB and ending 95 min.

- 3. 30 min ascent to 10.2 psia on 100% O2.
- 4. 30 min at 10.2 psia breathing 73.5% N2 and 26.5% O2
- 5. 17 min purge and leak check
- 6. 5 min on 100% O2, then descent to 14.7 psia.
- 7. 35 min in-suit PB
- 8. 20 min additional in-suit PB to compensate

for no in-suit Doppler

9. 30 min ascent to 4.3 psia

5.7863 2.88

2.8897

ETR360 = 1.3475 ETR180 = 0.672

Computed Effective TR360 based on observed DCS (0%) from Phase II PRP test.

Used upper 95% CL from Binomial Theorem of 6.5% for ETR360 = 1.445

Added 20 min additional PB for final ETR360 = 1.3475

Computed ETR180 based on total PB time needed to achieve ETR360 = 1.3475 (361 min), then used that time in 180 min half-time compartment to give ETR180 = 0.672



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Table I is a summary of the data, and the resulting logistic regression equations for the cuff classification. Figures 1 and 2 show the regressions.

TABLE I. DATA SUMMARY FOR DCS CUFF CLASSIFICATION

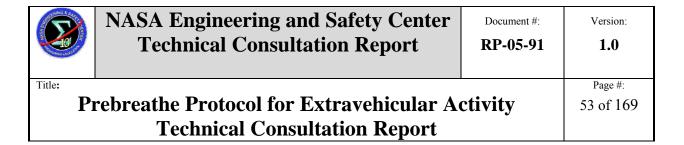
DCS category	n	DCS cases	source
cuff 1	914	89	NASA + USAF
cuff 2	914	24	NASA + USAF
cuff 4	914	5	NASA + USAF
cuff 4	6859	325	literature

It is important to understand how a simple index of decompression stress, called tissue ratio (TR or TR360) is computed. It forms the single most important variable in all the regressions to follow. Tissue ratio is the ratio of calculated $\rm N_2$ pressure in a theoretical tissue compartment just prior to the decompression to the final ambient pressure. Prebreathing 100% $\rm O_2$ or $\rm O_2$ -enriched mixtures prior to a hypobaric decompression is an effective and often used technique to prevent DCS. Therefore, it is necessary to account for the use of $\rm O_2$ -enriched mixtures prior to decompression in order to use the majority of information in the NASA/USAF database, and the literature data from the Hypobaric Decompression Sickness Databank (HDSD).

Equation 1 defines how P1N₂ is calculated; it approximates a more complex process of dissolved N₂ kinetics in living tissue. Following a step-change in N₂ partial pressure in the breathing medium, such as during a switch from ambient air to a mask connected to 100% O_2 , the N₂ partial pressure that is reached in a designated tissue compartment after a specific time is:

$$P1N_2 = P_0 + (P_a - P_0) * (1 - exp - k * t),$$
 Eq. 1

where $P1N_2$ = the N_2 partial pressure in the tissue after "t" minutes, P_0 = initial N_2 partial pressure in the compartment, P_a = ambient N_2 partial pressure in breathing medium, exp = base of natural logarithm, and t = time at the new P_a in minutes. The tissue rate constant "k" is related to the tissue N_2 half-time (t1/2) for N_2 pressure in a compartment, and is equal to 0.693 / t1/2, where t1/2 is the 360 minute tissue N_2 partial pressure half-time, and 0.693 is the natural log of two. The half-time compartment can also be estimated in the statistical regression. The initial, equilibrium N_2 pressure (P_0) in the tissue at sea level is taken as 11.6 psia instead of an average alveolar N_2 pressure of 11.0 psia. The use of dry-gas, ambient N_2 pressure as equilibrium tissue N_2 pressure (P_0), and as the N_2 pressure in the breathing mixture (P_a) makes the application of Eq. 1 simple.



The logistic regression equations for cuff 1, 2, 4, and cuff 4 from the literature data are:

$$P(\text{cuff 1}) = \frac{\exp(-1.222 + 3.552 * \ln(\text{TR - 0.78}))}{[1 + \exp(-1.222 + 3.552 * \ln(\text{TR - 0.78}))]}$$

$$Eq. 2$$

$$exp (-2.524 + 4.519 * \ln(\text{TR - 0.78}))$$

$$P(\text{cuff 2}) = \frac{\exp(-2.524 + 4.519 * \ln(\text{TR - 0.78}))}{[1 + \exp(-2.524 + 4.519 * \ln(\text{TR - 0.78}))]}$$

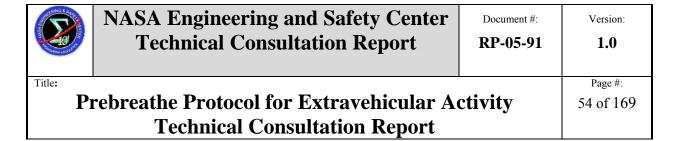
$$Eq. 3$$

$$exp (-3.701 + 16.489 * \ln(\text{TR - 0.78}))$$

$$P(\text{cuff 4}) = \frac{\exp(-3.701 + 16.489 * \ln(\text{TR - 0.78}))}{[1 + \exp(-3.701 + 16.489 * \ln(\text{TR - 0.78}))]}$$

$$Eq. 3$$

P(cuff 4) =
$$\frac{(TR - 0.90) 2.351}{[(TR - 0.90) 2.351 + 8.002 2.351]}$$
 Eq. 5



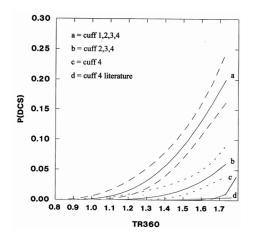


Figure 1. The probability of DCS with upper and lower 95% confidence intervals as defined in the cuff classification scheme as a function of tissue ratio from the 360 minute half-time compartment (TR360). Notice that cuff 1 (curve a) includes all cases that were diagnosed as DCS. Cuff 2 and 4 are subsets from cuff 1. Due to the limited NASA/USAF data on cuff 4, an analysis using data published in the literature was done to supplement the limited data. There is no curve for cuff 3 since that category of DCS was not available in the updated historical NASA/USAF database.

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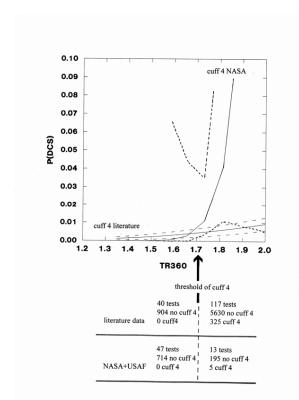
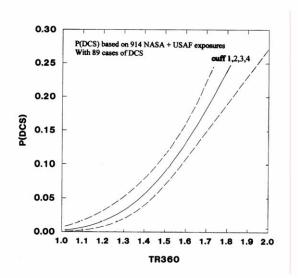


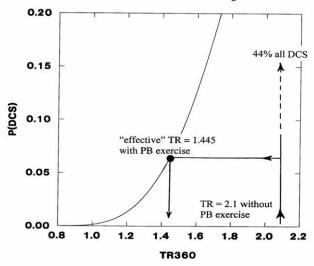
Figure 2. A comparison of the limited cuff 4 regression from the NASA/USAF data with cuff 4 from the literature data. Notice that the upper and lower 95% confidence intervals are large for the NASA/USAF data, reflecting the uncertainty in the true estimate of cuff 4 as a function of TR360. At a TR360 less than 1.70, there has not been a published report of a cuff 4. The regressions predict a low incidence of cuff 4 below 1.70, but this is an extrapolation into an area where there are no cases of cuff 4.

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"Effective" TR for Phase II given no DCS in 45 Exposures 95% confident that actual DCS is no greater than 6.5%



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4.0-hr In-suit as Flown (EVA3618.sys)

PN2 360 PN2 180

1. n = 4 4-hr in-suit protocols as flown 6.6994 3.9087

TR360 = 1.558 TR180 = 0.909



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NOT ALL DCS IS CREATED EQUAL- Concepts about DCS risk assessment

Due to the time it takes to terminate an EVA, return the astronaut to a safe pressure, and the consequences of a failed EVA, an evaluation of the time course of Type I pain-only DCS symptoms was initiated to help in decisions about terminating an EVA. The first question is do you stop an EVA at the <u>first</u> report of a "simple" Type I pain-only symptom based on the notion that a Type I DCS will evolve into a Type II DCS. Another question is will a Type I pain subside, or become intolerable to the point of interfering with the EVA. We evaluated the evidence on the time course of a pain-only symptom from the literature as well as our own experience at JSC.

In general, the onset of a symptom is not instantaneous and the risk of having a symptom increases with time. But it is unlikely that a person will get a symptom if he survives past some critical time since breathing 100% O_2 will ultimately reduce the N_2 pressure in the tissues. Also, some people with pain-only symptoms report that the intensity of pain reaches a peak, then subsides, and in some cases is completely gone before the end of a test.

Henry showed how the intensity of a pain-only symptom on a zero to nine scale changes through time in 15 males exposed to 3.0 psia (38,000 feet) for 90 minutes without prior O₂ prebreathing. He provided no details about the exercise done at 3.0 psia, or about the ascent rate. All 15 had DCS symptoms (100% failure) and the intensity of symptoms in six of the 15 (40% forced descent) was so great that they had to leave the chamber earlier than the scheduled 90 minutes. This test had a TR between 3.6 and 3.8. The onset time for a symptom was related to the maximum intensity of the symptom. The average onset time for the appearance of symptoms after reaching 3.0 psia that went only to two was 47 minutes, 42 minutes for three, 27 minutes for four, 23 minutes for five, and 19 minutes for greater than five. The more intense the pain the earlier the first report of the pain. Also in 11 of the 15 men that the intensity of the pain peaks after about 20 minutes then starts to subside. In the nine men that remained, only two still had symptoms at the end of 90 minutes. In summary, the earlier the onset of a symptom the greater the intensity of the symptom will be and if you can tolerate the peak intensity of the symptom it is likely that the symptom will subside. The author did not report any Type II symptoms in the 15 men, so it did not follow in these cases that sever Type I symptoms lead to Type II symptoms.

There are 42 cases of DCS in the NASA database that include information on how the intensity of a pain-only symptom changed through time. These cases come from 12 different tests with an average TR of 1.63 ± 0.18 (SD) and from three to six hour exposures to 4.3 psia. The subjects used a subjective zero to ten-point intensity scale to inform us on how pain-only symptoms changed during altitude exposures that were allowed to continue until loss of performance, our Type I Grade 3 classification. The subjects were immediately removed from the chamber when any Type II symptom appeared. There are more than 42 cases of DCS in the NASA database (82 at last survey), but not all records have the intensity scale and some tests did not allow subjects



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to proceed until loss of performance, plus some first had Type II symptoms and were not allowed to continue.

Table II shows the fraction of total cases of DCS where the intensity of symptoms decreased, increased, or stayed constant during the altitude exposure.

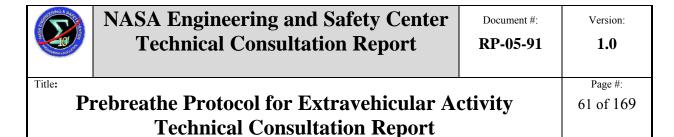
TABLE II: FRACTION OF SYMPTOMS WHERE INTENSITY INCREASED, DECREASED, OR STAYED CONSTANT

condition	cases / total records	fraction	TR360	SD
symptom got better with time	19 / 42	45%	1.64	0.13
symptom got worse with time	6 / 42	14%	1.58	0.20
symptom were consta with time	nt 17 / 42	41%	1.63	0.18

The TR is about the same for the three subsets of the 42 cases. A small fraction (14%) of the total DCS cases had symptoms that increased in intensity while the majority of symptoms improved (45%) or stayed constant (41%). There were only five subjects out of 42 cases of DCS (12%) that were removed from the chamber before the scheduled end of the test. Three of these were from the group of six where the intensity of the symptom increased with time. There were no cases of an aborted chamber test in the 19 subjects where symptoms got better with time. There were eight cases (8 / 42 = 19%) where the symptom was gone before the end of the test (seven of the eight were in the group of 19 where the symptoms improved with time), five cases (5 / 42 = 12%) where the symptom did not resolve until site pressure, one case with no information, and 28 cases where the average pressure for symptom relief was 7.55 ± 1.76 psia.

Figure 4 shows a plot of the intensity of the symptom versus the time at altitude in the 19 subjects with symptoms that improved. These are group results and it is not possible on Fig. 4 to track how each individual improved. Figure 4 shows both a two parameter linear regression and a three parameter nonlinear regression with a function that allows for an increase and then decrease in a response. Figure 5 shows how the intensity of the symptom increased in six subjects. There were three of these subjects that required removal from the chamber before the scheduled end of the test. Figure 6 shows the results from 17 subjects where the intensity of the symptom did not change, and only two of these subjects were removed before the end of the test.

It is clear from this brief survey that a full spectrum of responses is possible. A person may develop a symptom that increases, decreases, or remains constant during the altitude exposure. The symptom may resolve completely in some cases before the end of the exposure, on the way to site pressure, or still be present for some time at site pressure.



About one in ten subjects with pain-only DCS in our tests wanted to stop the test and seek relief from a painful situation, so only a small fraction with DCS wanted to leave the chamber. The same may be true for EVA in that not every report of a symptom need result in the termination of the EVA, maybe only 10%. If the EVA crewman reports a symptom that improves with time it is unlikely that the symptom will terminate the EVA at a later time. If the crewman reports a symptom that increases in intensity with time it may or may not terminate the EVA at a later time.

Finally, we did have the resolution in our data to describe a rise and fall in symptom intensity with time, but there were only two good cases of this pattern (see Fig. 4). It may be that we do not "stress" the subject enough, certainly not as much as was done during World War II. The above study from Henry (4) had a TR of between 3.6 and 3.8 while at JSC we tested a TR of about 1.65. Both data define a range of possible outcomes. In both cases, a "wait-and-see" approach allowed the chamber test to continue for the majority of the subjects (81% with DCS continued to the end of the test [46 / 57]) and this approach never resulted in more serious symptoms, even in those who eventually left the chamber due to an increased intensity of Type I symptoms (11 / 57). The same will likely be true for EVA crewman. This information gives the Flight Surgeon and Flight Director additional options to consider (based on experience) when the first Type I symptom is reported during an EVA.

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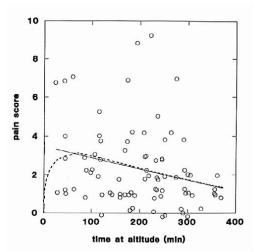


Figure 4. The intensity of Type I pain-only symptoms in 19 of 42 individuals with DCS decrease while at 4.3 psia. The plot shows the group results and it is not possible to see how any one individual responded. The regression line shows a trend but extrapolation to the y-intercept at time = 0 is meaningless. A function that starts at 0,0 then increases and then decreases with time was fitted to these data and shows that a rise and fall pattern in symptom intensity can be defined in these data.

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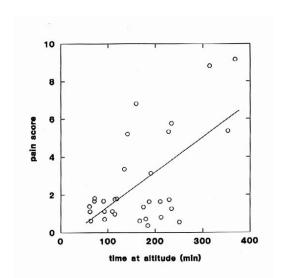


Figure 5. The intensity of Type I pain-only symptoms in 6 of 42 individuals with DCS increase while at 4.3 psia. Three of the six where removed from the chamber before the scheduled end of the test because of the increase in symptom intensity. Again, extrapolation to the y-intercept at time = 0 is meaningless.

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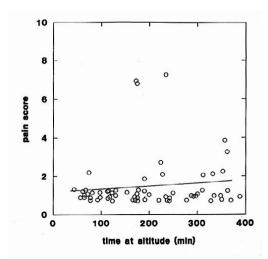


Figure 6. The intensity of Type I pain-only symptoms in 17 of 42 individuals with DCS stay constant while at 4.3 psia. The majority of constant pain was low intensity but you can also have high intensity constant pain.



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244 Literature Database Tests about Serious DCS Where Exercise was Done at Altitude

1	2	3	4	5	6	7	8
		(see	column de	efinit	ions below)		
421	6	0	4.3	180	1.68	0	0
220	12	0	4.3	180	1.112886224	0	0
221	12	0	4.3	180	1.370733504	0	Ö
222	12	0	4.3	180	0.94836177	0	0
66	12	0	7.34	1440	1.578303738	0	0
68	43	0	10	525	1.137892658	0	0
255	0	10	9.5	480	1.078377694	0	0
64	12	0	7.34	1080	1.578303738	0	0
62	12	0	7.34	720	1.578303738	0	0
118	17	0	5.45	120	2.112954007	0	0
116	17	0	8.63	120	1.333521115	0	0
127	7	0	3.47	180	1.309146639	0	0
99	11	0	5	120	1.194638363	0	0
422	0	1	4.3	180	1.68	0	0
423	7	0	4.3	180	1.68	0	0
340	6	0	4.8	150	1.795159053	0	0
336	15	0	4.2	240	2.318094641	0	0
335	143	0	5.4	120	2.027606725	0	0
334	68	0	5.8	90	1.936168617	0	0
341	14	0	4.8	330	1.795159053	0	0
342	17	0	3.5	180	2.390009162	0	0
49	116	0	9.7	240	1.174286245	0	0
289	23	0	3.87	300	1.682449204	0	0
436	8	0	4.3	240	1.77	0	0
437	0	2	4.3	240	1.77	0	0
355	10	0	8.3	360	1.386870241	0	0
346	6	0	3.87	180	1.817115931	0	0
345	6	0	5.95	60	1.875947525	0	0
100	11	0	5	120	1.17408256	0	0
101	17	0	3.8	120	2.147016992	0	0
233	9	0	8.5	360	1.325138682	0	0
235	0	11	9.5	360	1.188	0	0
252	0	10	9.5	480	1.085981821	0	0
253 254	0	10 10	9.5 9.5	480 480	1.078851488	0	0
60	12	0	7.34	720	1.252478204	0	0
55	6	0	9.7	240	1.174286245	0	0
234	6	0	9.5	360	1.186653869	0	0
239	11	0	4.3	360	1.040306182	Ö	Ö
243	0	14	6	360	1.226727962	0	0
245	Ö	11	8.3	360	1.373493976	Ö	0
246	12	0	9.5	480	1.2	0	0
247	12	0	9.5	480	1.085981821	0	0
248	12	0	9.5	480	1.078851488	0	0
249	12	Ö	9.5	480	1.07840558	Ö	Ö
250	11	0	9.5	480	1.078377694	0	0
232	8	Ō	10	360	1.127797823	Ō	0
231	16	0	9	360	1.252049475	0	0
157	69	0	4.25	360	1.828677542	0	0
97	11	0	5	120	1.590741791	0	0
98	11	0	5	120	1.302860804	0	0



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106 85 44 333 48 134 188 46 159 331 408 217 238 344 454 39 20 258 379 446 189 186 199 447 441 425 54 212 213 18 378 419 256 215 69 72 50 50 50 50 50 50 50 50 50 50 50 50 50	35 128 8 8 8 195 144 29 36 21 14 12 0 23 17 11 0 11 71 143 15 10 10 29 28 14 19 59 59 59 59 59 59 59 59 59 59 59 59 59	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	5.45 5.95 5.95 4.78 3.55 5.95 4.3 5.95 4.3 5.95 4.3 5.95 4.3 5.95 4.3 6.5 4.3 5.3 6.5 4.3 6.5 4.3 6.5 4.3 6.3 6.3 6.3 6.3 6.3 6.3 6.3 6.3 6.3 6	120 120 180 120 180 120 18 180 360 360 360 240 60 120 180 120 120 180 240 180 120 120 120 120 120 120 120 120 120 12	2.141727921 2.094703445 1.612322108 2.091234435 1.62881114 1.916094268 2.394296741 0.914251471 2.02051721 2.094718483 1.78 1.42 1.310639355 2.265769777 1.89 2.091743119 1.556849256 1.770926616 1.777757825 1.77 2.194589902 2.622414716 1.630491953 1.77 1.55 2.130551109 1.875218773 1.604223879 1.3553096924 1.646293101 1.777757825 1.68 2.040256197 1.81200589 1.665167798 2.0855062 1.648942425 1.91312809 1.906718301	11.4 11.8 12.5 12.5 12.5 12.8 13.8 13.8 14.3 16.6 17.6 18.2 18.3 19.6 20 20 20 20 20 20 20 20 20 20 20 20 20	000000000000000000000000000000000000000
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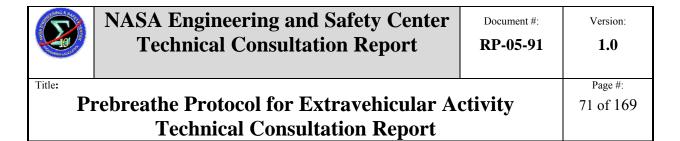
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372
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                            2.629997882 100
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- 1 = Report number in Literature DCS Database
- 2 = Total number of males in test
- 3 = Total number of females in test
- 4 = altitude (psia) where test was performed
- 5 = time (minutes) spent at altitude performing prescribed exercise
- 6 = the 360 minute half-time tissue ratio
- 7 = the percentage of total DCS for the test
- 8 = the percentage of serious DCS for the test

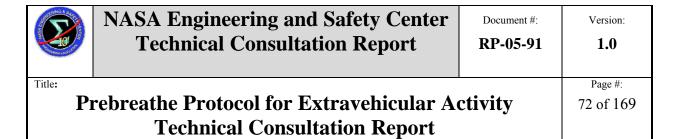
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Appendix D. "Acceptability of Campout Prebreathe Protocol for ISS EVA Operations"



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Acceptability of Campout Prebreathe Protocol for ISS EVA Operations





Campout Prebreathe Protocol

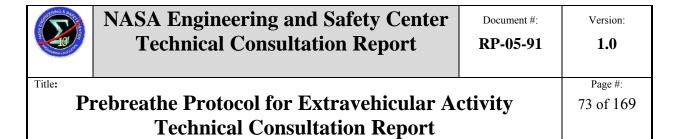
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- Overview of Presentation
 - Objective
 - Current Flight Rule
 - Prebreathe Protocols
 - » Description
 - » Brief History and Evolution
 - » Operational experience
 - Reliability of Verification
 - » Ground Based Tests
 - » Flight Experience
 - Additional Considerations
 - Summary Statements
 - Proposed Flight Rule Modifications



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Campout Prebreathe Protocol

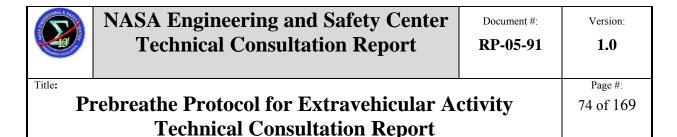
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· Objective:

- To review and determine the acceptability of the Campout Prebreathe Protocol for ISS EVA Operations
- Driven by MOD/XA operational desires on EVA day (e.g. time efficiencies, elimination of potential Scheduling Constraint violations)





Campout Prebreathe **Protocol**

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Current ISS Prebreathe Protocols

(Originally accepted by testing. Currently acceptable by analysis) - Four hour In-suit

(Accepted by analysis of related Campout

data/similarity to shuttle 10.2 psi staged

protocol)

(Accepted by testing utilizing the Exercise Prebreathe

criteria below)

Accept Criteria for ISS EVA Prebreathe Protocols*

- One-year "DCS Risk Definition & Contingency Plan" effort designated accept criteria of research protocol
 - » Decompression Sickness (DCS) ≤ 15 % at 95% CL
 - » Grade 4 Venous Gas Emboli (VGE) ≤ 20 % at 95% CL
 - » No Type II (serious) DCS

^{*} This criteria was not applied to the shuttle protocols



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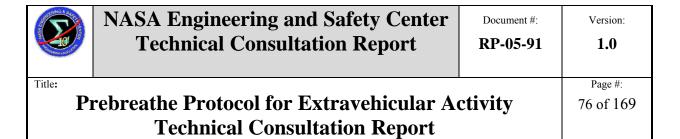
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- Current Flight Rule
 - EVA Prebreathe Protocol B13-107
 - » A. FOR ALL EVAS, PREBREATHING UTILIZING THE PREBREATHE HOSE ASSEMBLY (PHA) AND THE EMU WILL BE ACCOMPLISHED USING THE PROTOCOL AS DEFINED IN PARAGRAPH A.1 (EXERCISE), UNLESS THE PROTOCOL DEFINED IN PARAGRAPH A.2 (10.2 PSI/527 MMHG CAMPOUT), OR A.3 (IN-SUIT) IS REQUIRED
- Family of ISS Prebreathe Protocols historical approach
 - Exercise Protocol is "Primary" *
 - Campout and Four Hour In-Suit as "Backups"

*note: for shuttle 10.2 psi staged protocol is primary, because exercise protocol is not compatible





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- ISS Scenarios when alternate protocols might be utilized
 - Up to 21 single point failures with CEVIS, prebreathe hose assembly, or 10.2 psi depress infrastructure that could result in need for alternate protocol



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4-Hour In-Suit Prebreathe

 Begins after EMU is donned and purge completed, 4.0 hours of O2 Prebreathe (PB) must be completed prior to depress.

History and Evolution of 4 Hr In-Suit PB Protocol

- In 1982, 3.5 hour PB accepted based on shirtsleeve tests at 3.5 hours and 4.0 hours. Tests comprised 50 total exposures (n=22 at 3.5 hrs, n=28 at 4 hrs). DCS incidence at 3.5 hrs = 32%, 4 hrs = 21%. All simple limb bends.
- After 1986 Challenger accident, PB increased to 4 hrs. Model analysis
 of all JSC tests done to that time suggested risk for the 4-hr PB of
 approx. 24% (total incidence of symptoms), with approx 5% that would
 terminate an EVA. (Type II DCS or DCS which interfered with
 performance).
- Chamber Experience (EMU suited runs)
 - > 300 4-hr Exposures with DCS incidence < 1.5%, no Type II
- Operational experience
 - 2 person-exposures conducted with the 3.5 hr PB (STS-6)
 - 4 person-exposures conducted with the 4.0 hr PB (STS-57, STS-63)



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10.2 psi Staged Shuttle Protocol

- Protocol begins with 60 min of O2 PB prior to mask doffing at 10.2 psi
- Requires a minimum of 12 hrs at 10.2 psi with a nominal N2 pressure of 7.5 psi
- Completed with 75 min Final in-suit 02 PB before depress
- With a minimum of 24 hrs at 10.2 psi, final in-suit PB reduced to 40 min.
- With a minimum of 36 hrs at 10.2 psi, initial 60 min O2 breathing is deleted. (Final in-suit PB is 40 min.)



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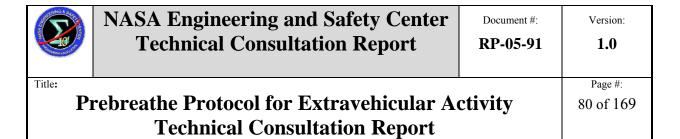
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History and Evolution of 10.2 psi Staged Protocol

- In 1982, 10.2 psi protocol (with 60 min. 02 PB prior to 10.2 depress, 12 hr stay, and 40 min final in-suit PB) was accepted for operations.
 - » Based on testing at JSC (BLD 7/ETA/overnight stay), (n=35) resulted in 23% DCS (simple limb bends, no type II)
- Post Challenger accident, to enhance safety, PB amended to improve N2 washout by either:
- (a) extending 10.2 psi stay from 12 hrs to 24 hrs, or
- (b) increasing final O2 PB from 40 min to 75 min. No direct testing completed on this amended protocol. [At that time, based on model analysis of all JSC tests, risk of DCS was estimated at approx. 24%, with a 5% risk of EVA termination.]
- In 1991, an option to 10.2 protocol was approved to allow deletion of first 1 hr mask PB when the 10.2 stay was greater than 36 hrs. (Operationally desirable.) Option allowed was based on analysis and expert consultation, without direct testing.



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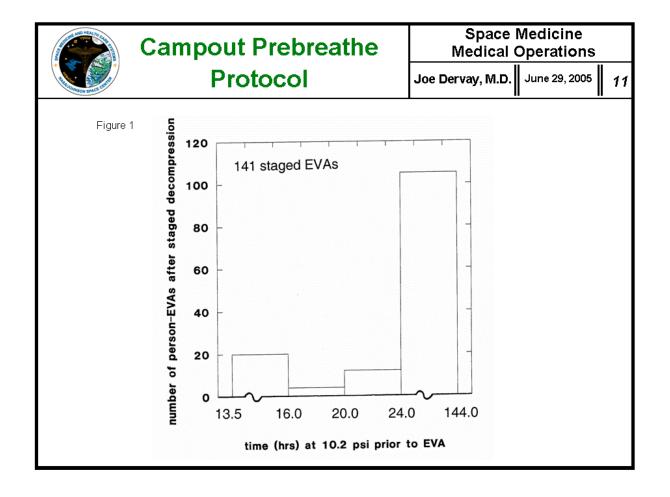
Operational Experience

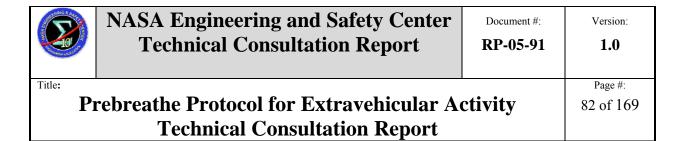
To date, there have been 141 person-EVAs conducted with 10.2 psi Staged PB Protocol Final PB

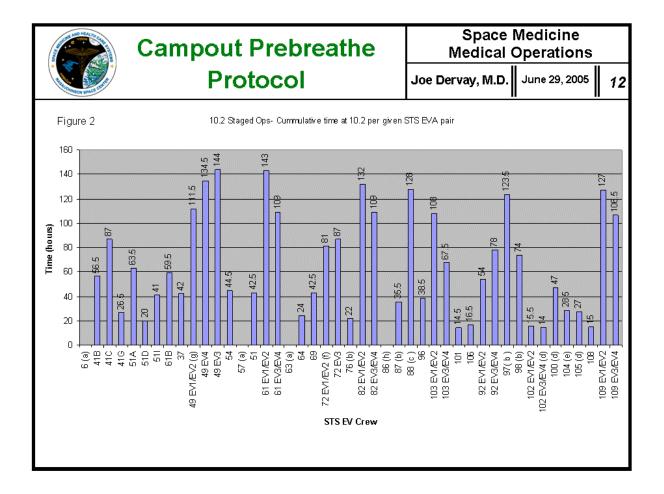
» 12-16 hr stay at 10.2 --- 20
 » 16-20 hr stay at 10.2 --- 4
 » 20-24 hr stay at 10.2 --- 12
 » 24 hr > stay at 10.2 --- 105
 75 min
 50 min
 40 min

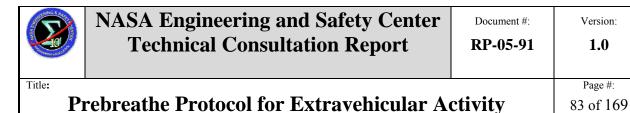
 In no case has there been any reported symptoms or signs of DCS

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Footnotes

- No depress to 10.2. STS-6 used 210 minute in-suit prebreathe. All others used 4 hour in-suit prebreathe.
- Time estimated from ODRC data, log unavailable STS-87(Shuttle airlock pressure). (b)
- Cabin repressed to 14.7 post-EVA2 and depressed to 10.2 pre-EVA3, STS-88. (c)
- Cabin repressed to 14.7 post-EVA1 and depressed to 10.2 pre-EVA2. (d)
- EVA 3 performed from the ISS Airlock. STS-104 (e)
- EV1 performed his second EVA with EV3, which was EV3's first EVA **(f)**
- (g) EVA 3 was a three-person EVA (EV1, EV2, & EV4).
- Shuttle-Wir Mission. Cabin pressure reduced to 12.64 psi for hatch opening. Final in-suit prebreathe was 169 minutes. STS-86.



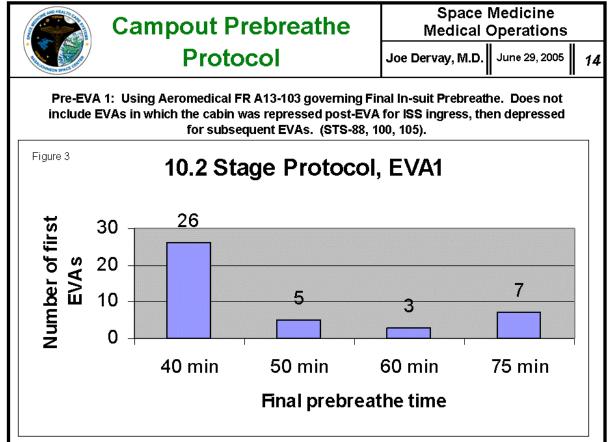
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Initial ISS Campout Protocol (1995)

 Required a 60 min initial PB prior to mask doffing at 10.2; 10 hr airlock stay at 10.2; waste management break (WMB) at 14.7 with mask 02 (60 min minimum on 02 during break/transit back to 10.2; minimum of 60 additional min back at 10.2 psi during suit donning, followed by 30 min Final in-suit PB

History and Evolution of the ISS Campout PB Protocol

- In 1995, Campout Protocol approved by "similarity" to Shuttle 10.2 psi protocol. Approval was concurred by SD5, SD2, SD and SA. Approval memo recognized that procedures were still in development, and anticipated possibility of further conservative "trades of time" at 10.2 for additional time on mask O2.
- 1999 subsequent changes in protocol: primarily due to slower airlock depress time than anticipated, increased total time on mask 02 by 20 min (10 with final PB, 10 with WMB). This allowed decreased time at 10.2 stay by 1 hr and 20 min. (Changes approved by Medical EVA IPT and forwarded to SD.)



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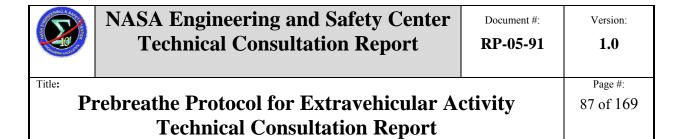
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Exercise Prebreathe Protocol Description

- Includes 2- hrs. and 20 min of O2 PB with 10 min during moderately high exercise (75% VO2 max). Final period of 60 min in EMU (extended from tested 40 min as addition safety margin since on-orbit in-suit Doppler not available)
- History and evolution of Exercise PB Protocol
 - Approved in 1999 based on multi-laboratory altitude chamber study.
 Study had well defined acceptance criteria and met these criteria with no incidence of DCS in 45 subjects. Test produced the lowest incidence of DCS of any test of a PB protocol at JSC. Study and protocol received high level of scrutiny, and approval was concurred upon by all levels of JSC and HQ management.
- Operational experience
 - 34 person EVAs (17 individuals) have been conducted with protocol
 - No DCS has been reported on any EVA



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- In-Suit Exercise Prebreathe --- Current research initiative
 - Duke University, DRDC Canada
 - Evaluating use of intermittent exercise in the EMU



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Prebreathe Protocol	Observed Risk (total DCS) Ground Trials	Flight Experience	Predicted Risk Accounting for Flight Factors* (microgravity, purge, leak check, depressurization rate, etc.)	Predicted Risk (serious Type II DCS) Accountin for Flight Factors*
EXERCISE (CEVIS)				
N	45	0/34		
DCS	0% (≤6.5% @ 95% cl)**		1.7% (≤4.0% @ 95% ci) ***	1 / 4972 (1/3447 – 1/8928 ci)
Grade IV VGE	6.6% (≤16.3% @ 95% cl)		3.8% (≤12.4% @ 95% ci)	
4.0 HOUR (In-suit)				
N	28	0/4		
DCS	21% (≤38.0% @ 95% cl)		4.6% (≤9.4% @ 95% ci)	1 / 1372 (1/960 – 1/2402 ci)
Grade IV VGE	39% (≤56.6% @ 95% cl)		9.9% (≤ 32.2% @ 95% ci)	
CAMPOUT (ISS)				
N	No direct ground tests	N/A		
DCS			2.8% (≤5.9% @ 95% ci)#	1 / 936 (1/656 – 1/1635 ci)#
Grade IV VGE			5.8% (<19.0% @ 95% ci)#	
10.2 PSIA STAGED				
N	35	0 / 141		
DCS	23% (≤37.5% @ 95% cl)		3.8% (≤ 7.6% @ 95% ci)	1 / 311 (1/217 – 1/549 ci)
Grade IV VGE	23% (≤37.5% @ 95% cl)		8.0% (≤ 26.0% @ 95% ci)	

^{*}Includes operational margin, microgravity simulation (non ambulation), accounts for exercise with CEVIS protocol. Published/peer-reviewed models.

^{**}cl is upper 95% binomial confidence limit, based on observation of test result.
***ci is the upper part of the 95% confidence interval, based on a statistical regression.



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Campout Prebreathe Protocol

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- Prebreathe Protocols Observed and Estimated Risks
 - The best estimates for DCS for <u>all</u> the prebreathe protocols meet the accept criteria use on ISS
 - » DCS < 15% @ 95% CL
 - Only the Exercise Protocol (test and analysis) and the modified Campout Protocol (analysis) meet the accept criteria for Grade IV VGE
 - » Grade IV VGE <20% @ 95% CL
 - The Shuttle 10.2 psi staged protocol and the 4 hr. protocol have been deemed acceptable by flight and suited chamber experience.



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Campout Prebreathe Protocol

Space Medicine Medical Operations

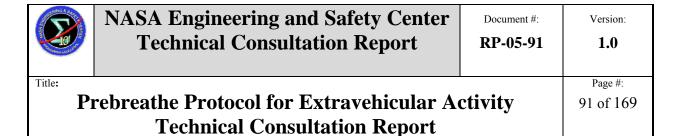
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Reliability of verification – Ground based tests

- Exercise Protocol: historically the most stringent ground-based verification, with the lowest incidence of DCS.
- 4-hr PB Protocol, and Campout Protocol (by similarity to the 10.2 Staged protocol) have had less ground-based verification, and were accepted at higher rates of DCS than would currently be accepted.
- 4-hr & 10.2 Staged were tested without microgravity simulation (non-ambulatory chamber run), which JSC investigators believe would have reduced the incidence of DCS.
- 4-hr & 10.2 Staged involved resting PB. If low-level work performed during suit donning, and other suit overhead activities were simulated during testing, investigators would expect lower incidence of DCS.



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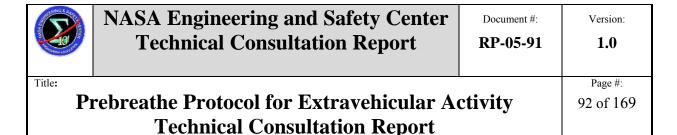
Campout Prebreathe Protocol

Space Medicine Medical Operations

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- Reliability of verification Flight Experience
 - 34 person-EVAs with the Exercise Protocol no reported DCS
 - 2 person-exposures with 3.5 hr PB, 4 person- exposures with 4 hr PB – no reported DCS
 - 141 EVAs with 10.2 Shuttle Staged Protocol: most uses at > 36 hrs stay at 10.2 - no reported DCS
 - Campout no direct flight experience (similarity to shuttle 10.2 psi staged protocol)





Campout Prebreathe Protocol

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Special Concerns & Mitigating Factors

- Campout modifications have extended mask 02 breathing time and have reduced the predicted DCS risk.
- With Campout, a greater portion of the 10.2 PB will be conducted during sleep, when metabolism is low, and thus the effectiveness of N2 washout may be lower. (campout – 60% sleep, shuttle 30% sleep)
- The "resting" metabolic overhead in the suit is more than the resting metabolic rate for shirtsleeve trails. Increased metabolic rates improve N2 elimination and add safety margin.



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Summary Statements

- The three protocols currently in the Flight Rules remain acceptable for mission use.
- All Prebreathe Protocols have a very low risk of more serious DCS, but in no case is that risk zero. Procedures are in place to deal with and ameliorate such an incident (DCS Treatment -Malfunction Procedures & Medical Checklist), however such an incident could obviously have major mission impact.
- The highest confidence, and the lowest prediction of risk, exist with the Exercise Protocol.
- Acceptability of the Campout Protocol is by analysis of related data and similarity to shuttle 10.2 psi staged protocol.
- 10.2 psi staged protocol is the best available protocol for shuttle EVA.
- The modified Campout Protocol is designed to be analytically more conservative than the 10.2 psi shuttle staged protocol.



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Proposed Flight Rule B13-107 modifications

- Consensus of Opinion --The Bioastronautics EVA IPT recommendations to the proposed flight rule were derived with concurrence from JSC personnel knowledgeable and expert in Hypobaric/Hyperbaric physiology and DCS.
- After several iterations, a final proposed version of Flight Rule B13-107 was achieved 4/13/04 through consensus of the Bioastronautics EVA IPT, and representatives of DA (Flight Directors' Office), CB reps (Astronaut Office), and XA (EVA)
 - » Flight Rule and rationale on following page
- Concurrence further received by:
 - » SD2 MED OPS/Fit Surgeons
 - » Space Medicine Configuration Control Board (SD/Dr. Duncan)
 - » SA/Director, Space & Life Sciences (Decision Memo-1st iteration of Flt Rule)



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Final version completed 4/13/04 at Bioastronautics EVA IPT. Consensus reached with IPT members, DA reps (Curry & Englehauf), CB reps (Tanner & Piper). Endorsed at MEDOPS mtg 4/14/04.

THE EXERCISE PREBREATHE (PB) PROTOCOL, 4 HOUR IN-SUIT PB PROTOCOL, AND CAMPOUT PB PROTOCOL, ARE ALL ACCEPTABLE FOR USE ON ISS WITH VARYING DEGREES OF DCS RISK UNCERTAINTY. THE SELECTION OF A PB PROTOCOL FOR A GIVEN EVA WILL DEPEND ON THE INTEGRATED MISSION OBJECTIVES, DECOMPRESSION SICKNESS (DCS) RISK, CREW TIMELINE, AND OVERALL OPERATIONAL RISKS.

The PB protocol selected for a given EVA event should consider all the factors affecting risk to the crew and mission. Predicted risk of DCS, procedural risk due to timeline complexity or fatigue, and criticality of completing the EVA tasks within a specified timeframe are all factors that must be weighed.

The PB protocols are ranked according to their pedigree based on laboratory testing, on-orbit and suited vacuum chamber experience, and model predictions.

1. Exercise PB Protocol:

Rationale: The Exercise PB protocol meets the current DCS acceptance criteria, is the most rigorously laboratory tested, and the protocol with the lowest predicted risk of DCS. (This acceptable risk was defined in the NASA DCS Risk Definition & Contingency Plan, 1998, (total DCS ≤15% at 95% Confidence Limit (CL), ≤ 20% Grade 4 VGE at 95% CL, No Type II (Serious) DCS.)

2. 4 hr In-Suit PB Protocol:

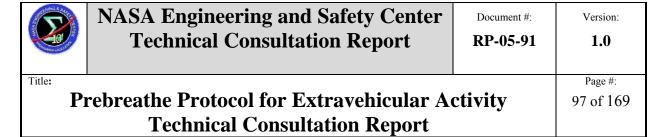
Rationale: The 4 Hr In-suit PB protocol has been extensively used on ground suited vacuum chamber exposures (> 300 exposures), with acceptable DCS risk (< 1.5% total DCS observed, no Type II). However, it has not undergone the same level of laboratory testing as the Exercise PB.

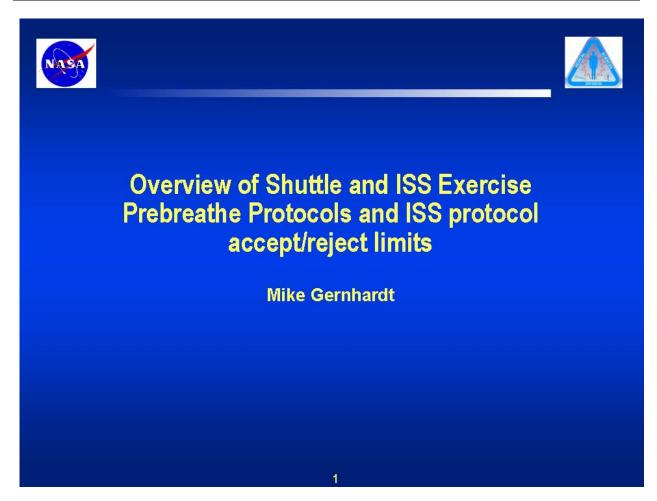
3. Campout PB Protocol:

Rationale: Model predictions and similarity to the Shuttle 10.2 psi staged-protocol show this to be an acceptable protocol, but with some increased risk, and greater uncertainty, compared to the Exercise PB Protocol. There is no direct laboratory testing, suited vacuum chamber, or direct on-orbit experience with the Campout protocol. However, this protocol was designed to be more conservative (as analytically determined) than the currently published shuttle 10.2 prebreathe protocol. (Ref. A13-103, EVA Prebreathe Protocol)

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Appendix E. "Overview of Shuttle and ISS Exercise Prebreathe Protocols and ISS Protocol Accept/Reject Limits"







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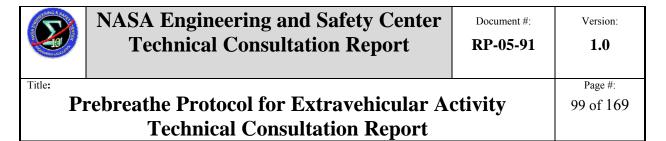
Altitude DCS Symptoms

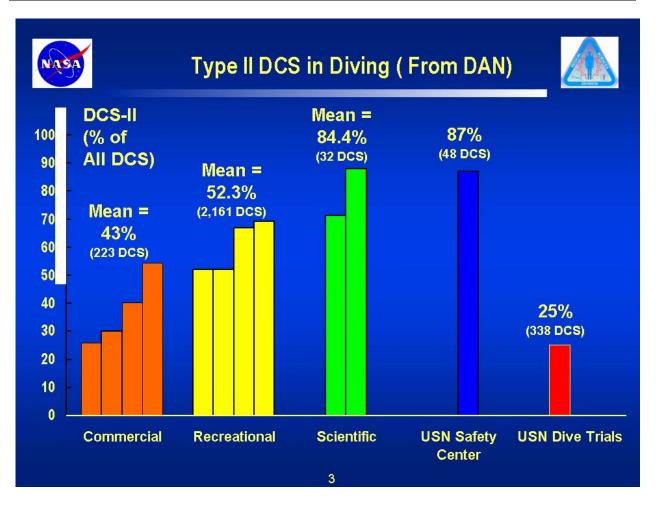
This table lists <u>ALL</u> DCS symptoms from the 989 subject-exposures with DCS from Brooks High Altitude Protection Laboratory

Symptom Grouping	<u>Symptoms</u>	% of All Symptoms
Pain	1124	74
Skin Mottling	31	2
Paresthesia	254	17
CNS	60	4
Pulmonary	43	3
Other	17	1
All Symptoms	1529	100

Note: Many subjects had more than one exposure and some had more than one type of symptom on any one exposure, e.g. 60 CNS symptoms were found in the database for all subjects and all subject-exposures

Note: These were high decompression stress exposures (average 40% DCS), some with no prebreathe. The incidence of type II DCS decreases with overall exposure severity (NASA tests \sim 1% type II DCS)







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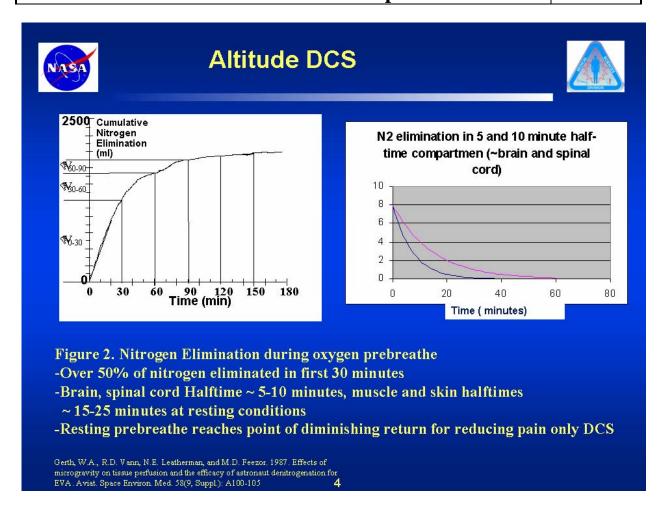
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Altitude vs. Diving DCS



- Far fewer type II symptoms in altitude vs. diving exposures
 - 4% CNS symptoms vs. ~30-50% in diving depending on exposure
 - ~ 1% in NASA prebreathe testing
- Most altitude exposures use 02 prebreathe prior to ascent
 - 5 of 6 cases of type II DCS at JSC occurred on zero prebreathe exposures
- Altitude Bubbles contain higher percentage of metabolic gases (~35% 02,C02, H20) than diving bubbles.
 - Softer Bubbles in terms of pathophysiological effect
 - Neurological tissues typically under saturated vs. supersaturated in diving exposures
 - Arterialized bubbles enter under saturated vs. supersaturated condition



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Ground-Level Treatment with 100% Oxygen (GLO2)

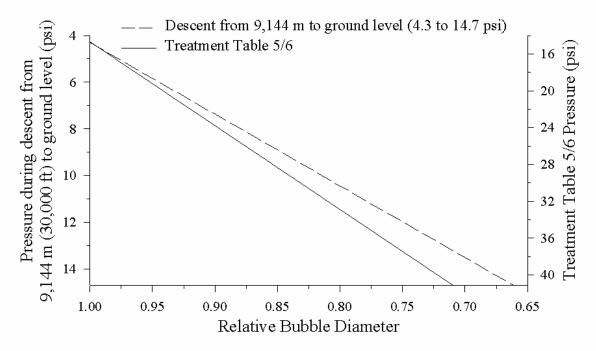


- Krause et al., 2000
- 2001 altitude exposures
 - 801 with DCS (40%)
 - **39 HBO**
 - 749 GLO2
 - 728 asymptomatic at ground level (GL)
 - >10 recurrence or delayed symptoms (1.4%)
 - 21 began GLO2 w symptoms unresolved at GL
 - >No recurrence or delayed symptoms (0%)
 - 98.7% success with GLO2

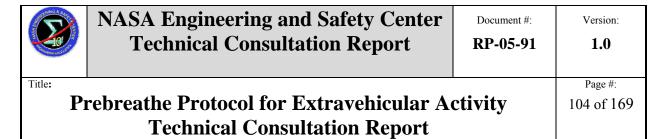
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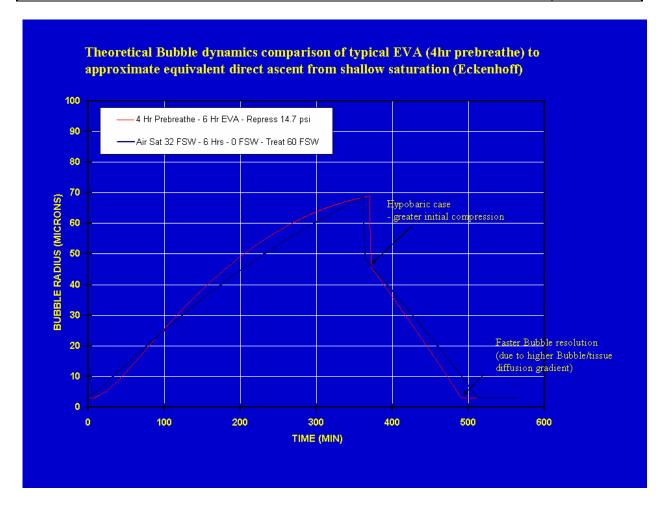
Figure 2

GAS BUBBLE SIZE REDUCTION COMPARISON



Treating DCS at 14.7 psi (from 4.3 psi exposure), is







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Shuttle Protocol Ground Trials



- Various protocols were tested to arrive at flight approved flight prebreathe protocols
 - 3 hr, 3.5 hr and 4 hr. prebreathe, 10.2 psi staged protocol (with and without 02 prebreathe prior to 10.2 psi depress)
 - DCS incidence on individual tests ranged from ~ 20%-36%
- EVA simulations were developed to model shuttle contingency tasks associated with failures of the payload bay doors and latch mechanisms:
 - Subjects ambulatory
 - Tasks with high joint velocities and range of motion





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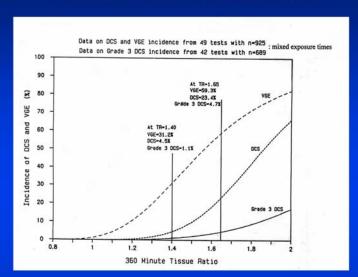
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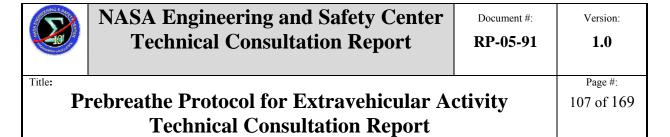
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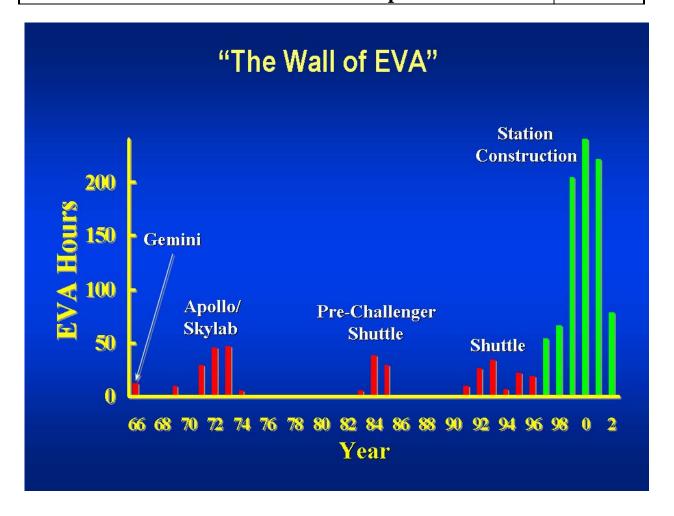
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Shuttle Prebreathe Ground Studies



- •Two Prebreathe protocols approved for flight operation
 - 4 hour in-suit resting oxygen prebreathe
 - 12 hr 10.2 psi staged decompression procedure
- R value (tissue tension (360)/suit pressure)= 1.65
 •Flight 10.2 staged protocol was based on R-value, not exactly like
- the ground tested protocols
- •Flight experience, 146 EVAs with no reports of DCS







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ISS baseline- Overnight Air Lock Campout at 10.2 psi



- Not able to depress Space Station to 10.2 psi
 - Overnight airlock campout at 10.2 psi baseline protocol for the ISS
- Many limitations including:
- crew isolation
- over 2 hrs on the mask
- two 10.2 psi depress/repress cycles on the limited life depress pump
- no waste management or hot food
- high 02 usage- requirement for 12 EVAs per increment not possible
- multiple hatch 02 hose drag through during hygiene break
- a loss of flexibility if you are not able to go into campout on time on docking day, or on subsequent EVAs
- risk of breaking ISS 02 % limits if multiple campouts per mission is performed,
- tight ECLSS monitoring requirements with numerous single point failures (MCA)
- No direct testing shorter duration at 10.2 psi than shuttle experience (< 10 hrs vs. > 40 hours)
- 60% of time sleeping with low metabolic rate and reduced N2 elimination.





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Prebreathe Reduction Program



- Initiated in late 1997 to address the limitations of campout
- Objective: Develop, test, certify and implement a 2hr prebreathe protocol for EVA from ISS by July 1999 (the installation and first use of the ISS joint airlock)
 - Reduce the prebreathe time by 50% over the 4 hr protocol and maintain or increase the safety margins
 - Enabling research protocols were not operationally feasible (too long or very high DCS risk)
- Develop an integrated decompression system, not just a prebreathe protocol
 - DCS disposition Policy, improved treatment protocols, definition of acceptable DCS risk, reduced prebreathe protocol with improved safety, integrated longer term research plan



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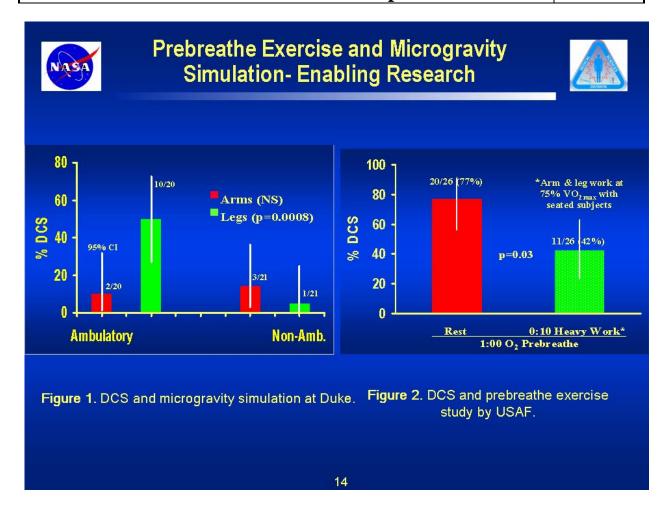
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Pre-EVA Deep Knee Bends



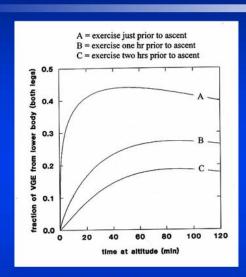


Figure 3. DCS and post-exercise recovery

A NASA JSC study (3) found that extended post-exercise resting recovery periods following 150 deep knee bends completed in 15 minutes significantly decreased the ∨enous gas emboli (VGE) during subsequent depress to 22,000 feet (Figure 3). (Dervay, Powell).



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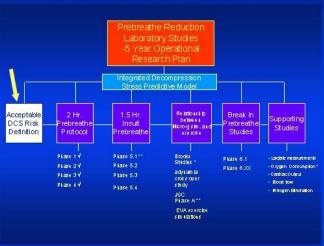
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Structure of Five Year Research Program





- Start by defining acceptable DCS risk for ISS mission and developing accept/reject limits for countermeasure trials
- Early development focused on delivering acceptable/effective counter measure
- Later development focused on increased efficiency and improved scientific understanding of counter measure mechanisms
- Concept of a family of protocols that could be used to provide operational flexibility



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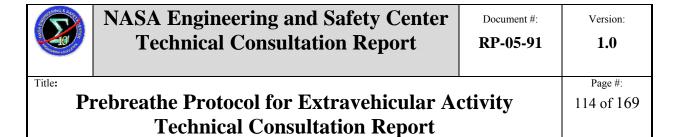


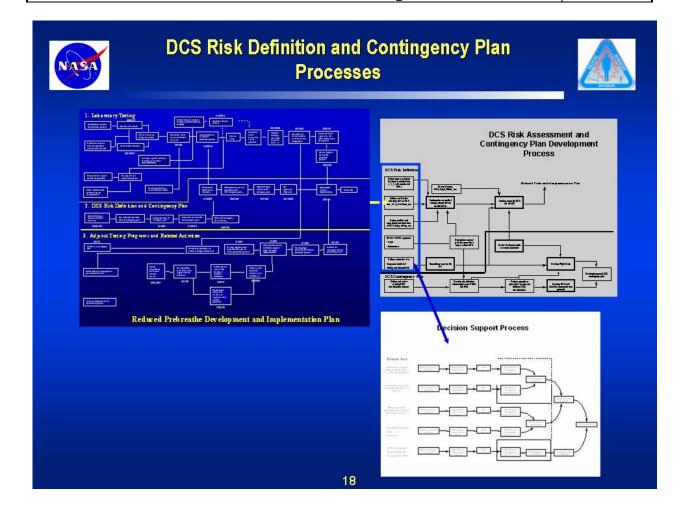
DCS RISK DEFINITION AND CONTINGENCY PLAN



Defining Acceptable DCS Risk.

- Can not define acceptable DCS risk without quantifying the on-orbit treatment capability
 - Required the development of a DCS contingency plan
 - Includes operational and medical responses to occurrence of different classifications of DCS
 - Includes a DCS disposition policy (what happens to a crew member if they have different classifications of DCS)
- The DCS Contingency Plan and disposition policy were prerequisites for quantifying the acceptable DCS risk for the ISS mission







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DCS RISK DEFINITION AND CONTINGENCY PLAN

- Assembled team of scientists, flight docs, crew members, MOD personnel, flight directors, statisticians and outside agencies involved with similar operations (USAF, USN)
- One year rigorous, data driven process
 - Systematically define the issues and mission drivers that affect acceptable risk
 - Collect and analyze historical data focused toward the key drivers
 - Determine the medical and operational impacts of different risk levels
 - Developed much improved on-orbit treatment protocols
 - Crewmembers remain under pressure (4.3- 8 psi over ambient) breathing 02 vs. ambient pressure air break (30+ mins) followed by 8.3 psi 02 in the suit.
 - Established clear DCS disposition policy (JPG 1800.3)
 - One Type I DCS, go for EVA in 72 hours
 - Second Type I DCS, or Type II DCS, out of rotation without AMB waiver
 - Establish Fight rules for prebreathe procedures and DCS management



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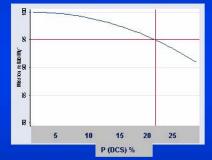
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DCS RISK DEFINITION AND CONTINGENCY PLAN



- Applied DCS disposition policy to the EVA assembly and maintenance model of the ISS (~484 EVAs from shuttle and ISS).
- Defined <u>highest</u> DCS risk consistent with a 95% probability that
 2 of 3 crew members would always be available for EVA
 - Highest DCS risk 21%
- Acceptable DCS risks were further reduced to account for related medical factors
 - On-orbit treatment
 - Delay of 30-45 minutes for re-pressurization
 - PFO considerations (added grade IV VGE)
 - Long term health risks



 Subjected DCS and grade IV VGE to constraint that they be below a threshold at where there has ever been a report of type II DCS in the literature



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Accept/Reject limits for Prebreathe Trials



- The mission driver of 95% probability that 2 of 3 crew members available for EVA throughout ISS program, combined with additional medical/operational considerations resulted in the following accept/reject limits:
 - Accept: DCS ≤ 15% and Grade IV VGE ≤ 20%, @ 95% c.l.
 - Reject: DCS > 15% or Grade IV VGE > 20%, @ 70% c.l.
 - Any case of Type II DCS
- Peer reviewed by the Lambersten Committee. More conservative:
 - than any previous EVA prebreathe trial including a 6 hr. prebreathe
 - All trials of shuttle EMU and Russian Orlan prebreathe protocols
- Closed (200 trials) sequential, multi-center trial, informed consenting subjects representative of astronaut population (age, gender, fitness, % body fat)
- 50 trial minimum to control type II error to less than 1%
 - Review of the data, continuation of the trials if Probability of future acceptance > 50%
- Planned for testing up to four protocol options



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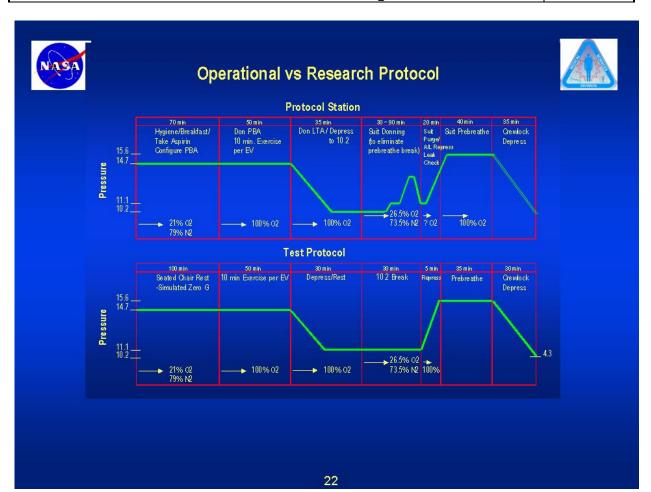
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Multi-Center Study NASA,Duke, DCIEM, Hermann UT





2hr oxygen prebreathe



Exercise 10 mins @ 75% V02_{peak} And/or light exercise (160-253 Kcal/hr) Micro-gravity simulation (non ambulation)



Simulated EVA exposure at 4.3 psi 4 hrs



Use of "Suit Simulator" for EVA Exercise



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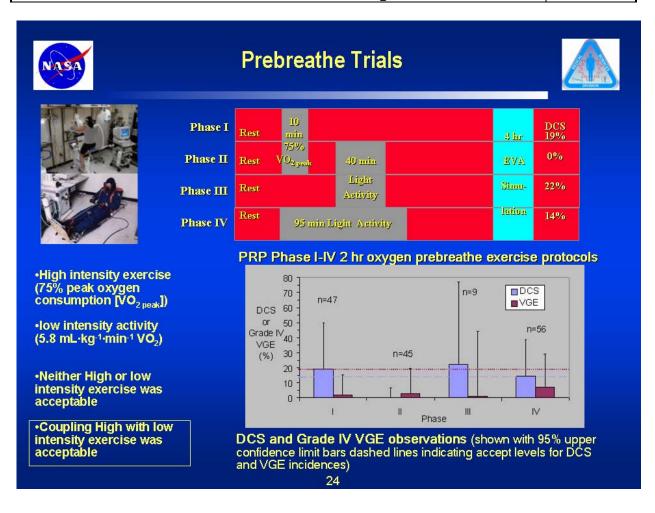
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"Operational Safety Margin"



The crews never do less than the specified prebreathe times, and frequently do more, driven by operational conditions * problems with 10.2 depress procedures, "A/L repress problem," Mask fit and flow problem "Helmet mic adjustment "Boot fit Broken bungee Trouble opening hatch depress DTO" Crew lock depress valve problem

Nominal time	80 min	20 min	30 min	60 min	30 min
Actuals	80-124 (88)	20-45 (30)	42-104 (61)	60-64 (60.3)	33-70 (39)
MISSION	MASK P.B	10.2 DEPRESS	TIME @ 10.2 PSI	IN-SUIT PB	DEPRESS
STS-104-1	97	45*	59	60	70*****
110-1	95*****	30	45	60	40
110-2	80	26	63	60	43
110-3	80	23	46	60	40
110-4	124 ^{±±}	74	32	60	41
111-1	82	24	81	60	41
111-2	87	34	70	60	39
111-3	80	25	61	87****	33
112-1	102***	29	87	60	43
112-2	80	25	62	60	42
112-3	80	24	53	61	38
113-1	94	25	60	60	35
113-2	81	21	49	60	37
113-3	80	25	104****	60	42
Exp.4-1	85	20	42	60	59*****
Exp-6	87	29	63	64	57*****



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Ground vs. Space



- •Shuttle ground trials 8/35 DCS (22.8%) vs. 0/141 DCS in Space significantly different (Fishers Exact test p<0.05).
- •Exercise protocol ground trials 0/45 DCS vs 0/34 in Space.

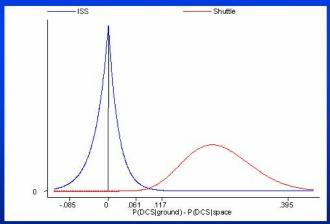
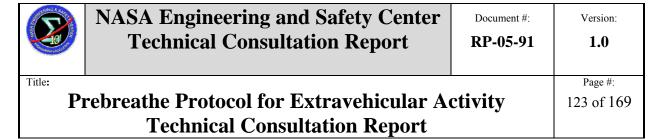
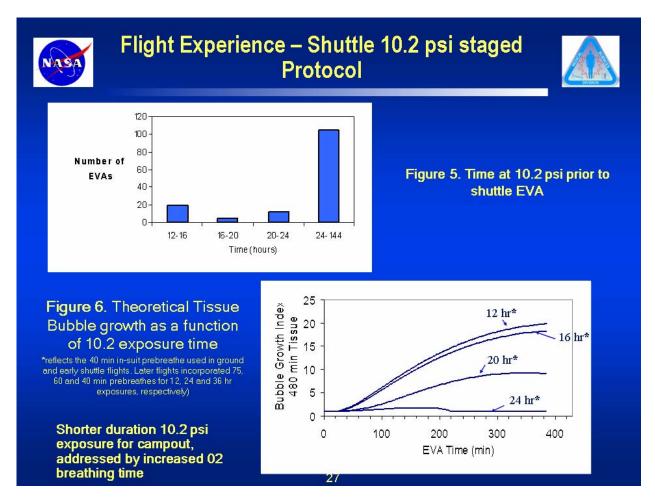


Figure 4. 95% Bayesian Confidence limits for P{DCS|ground}-P{DCS|space}

- Using uniform priors, the 95% Bayesian confidence limits for the risk difference (P{DCS|ground}-P{DCS|space}) were 8.5 to +6.1% for the ISS protocol and +11.7 to +39.5% for the Shuttle protocol.
- The point estimates of the differences were 0% - ISS protocol and +22.9% shuttle protocol.
- Results suggest that the Shuttle ground simulation overestimates the DCS risk in EVA, while the ISS ground EVA simulation provides an accurate prediction of the DCS risk in EVA (including the possibility that there is zero difference between ground and space).







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Evolving Prebreathe Protocols



- The exercise prebreathe protocol has worked well and solved numerous potential problems, but is not perfect and was not the final goal of the prebreathe reduction program
 - Relatively complex procedures
 - Complicated infrastructure with up to 21 single point failures
 - (CEVIS ergometer, prebreathe hose and mask, 10.2 depress etc.)
- In suit exercise protocol in development to address the limitations of the current CEVIS exercise protocol
 - Many constraints with performing the exercise in the suit
 - To date we have come close but not yet achieved a successful protocol
- Campout addresses some of the limitations of the exercise protocol, while introducing other limitations.



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Appendix F. EVA Camp-Out Prebreathe Protocol Peer Review Team Charge

The objective of this consultation is to review the physiological, modeling and operations data related to ISS EVA Camp-Out Prebreathe Protocol DCS risk and to assess the appropriateness of the draft JSC flight rule regarding the use of the ISS EVA Camp-Out prebreathe protocol.

The exercise prebreathe protocol used currently on ISS for reducing the amount of nitrogen in the spacewalking crewmembers' bodies prior to performing space walks from the ISS airlock has considerable ground testing and modeling and has been used successfully for several years on the ISS. The EVA Camp-Out prebreathe protocol has existed for many years, but it has never been used on-orbit and it has not had as much ground testing to validate it. It is however very similar to the 10.2 psia protocol that has been successfully used for most of the EVA's performed from the Space Shuttle airlock and it does have some day-of-EVA time saving advantages over the currently used protocol. Some future assembly crews and flight control teams would like to use this EVA Camp-Out prebreathe protocol because of this time savings advantage. The management of the Shuttle and Station programs has requested that an independent review of the DCS risks associated with the EVA Camp-Out prebreathe protocol be conducted. Feedback as to the acceptability of the EVA Camp-Out prebreathe protocol is requested before the programs are willing to consider it for use on future missions.

The findings and observations are to be documented in a written report and out-briefed to the NESC Review Board and the stakeholders.

The review team is asked to consider the following questions:

- 1. Is the ISS EVA Camp-Out prebreathe protocol acceptable for use in nominal operations? To answer this question, please consider the available ground testing data for validation, modeling, and the similarity/applicability to the Shuttle 10.2 psia protocol with its associated ground validation, modeling, and flight experience. In this context "nominal operations" means that EVA Camp-Out prebreathe protocol would be considered equivalent to the other prebreathe protocols and would be an acceptable choice for mission planning and use.
- 2. If the answer to the question in #1 is no, then is there a set of limited or restricted circumstances or off-nominal operations where the EVA Camp-Out prebreathe protocol would be considered acceptable? In these circumstances, balancing risk across all ISS

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operations including timeline would need to be considered by the flight control team in planning when to use the EVA Camp-Out prebreathe protocol.

- 3. If the answer to the question in #1 is yes, then are the differences in predicted risk between the prebreathe protocols of operational significance and how should the flight control team consider these differences in predicted risk for mission planning/decision making? To answer this question, please consider the available ground testing data for validation, modeling, and flight experience of the various prebreathe protocols.
- 4. Is the proposed flight rule B13-107 an acceptable approach to aide the flight control team in mission planning/decision making?

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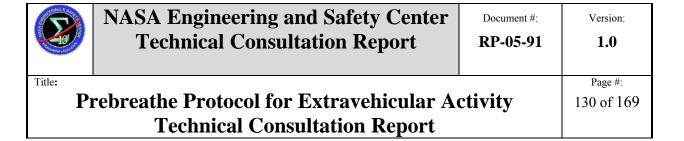
Appendix G. "Estimated Risk of DCS and VGE in ISS Campout Prebreathe"

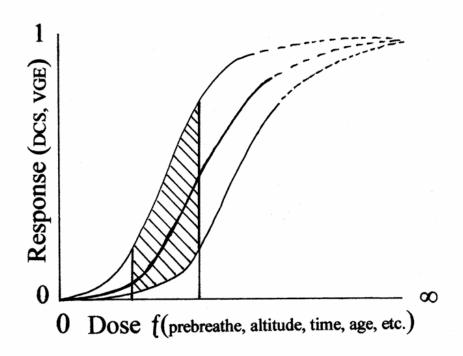
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Estimated Risk of DCS and VGE in ISS Campout Prebreathe

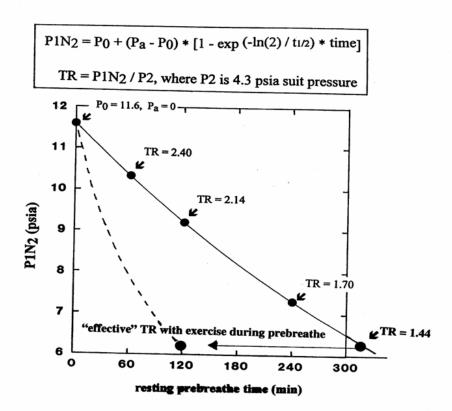


Johnny Conkin, Ph.D. Environmental Physiology Laboratory SK2 / NSBRI June 29, 2005





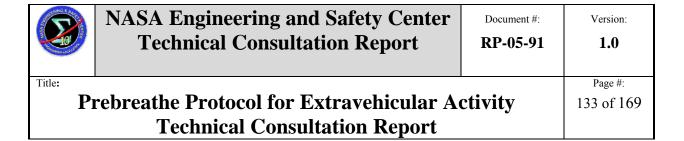
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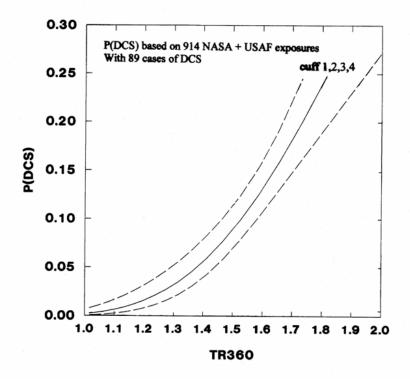


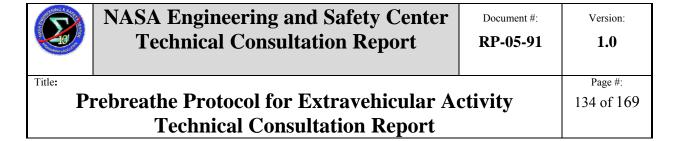
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four statistical models

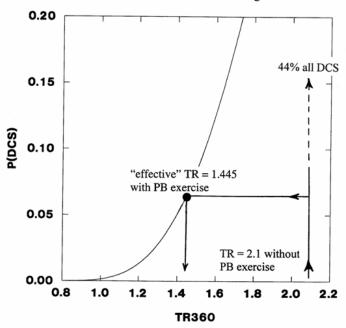
- P(DCS) f (TR360, LBA, Exercise)
 - published, n=1,401 with 76 exposures including LBA
- P(DCS based on cuff classification) f (TR360)
 - unpublished, n=914 NASA + USAF exposures
 - exposure times and exercise similar to EVA
- P(Grade IV VGE) f (TR360, LBA, AGE, Time)
 - unpublished, n=549 NASA exposures
- P(Serious DCS) f (TR180, Exercise, Time)
 - published, n=79,366 exposures with 918 serious DCS

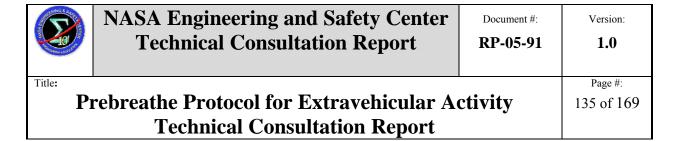






"Effective" TR for Phase II given no DCS in 45 Exposures 95% confident that actual DCS is no greater than 6.5%





Prebreathe Protocol	Observed Risks Flight (total DCS) Experience Ground Trials DCS / EVAs	Predicted Risk (total DCS) from <i>analysis</i> of flight factors*	Predicted Risk (serious Type II DCS) from <i>analysis</i> of flight factors*
EXERCISE (CEVIS)			
Ν	45 with LBA, ETR = 1.44 0 / 34	with LBA, ETR = 1.345	wo LBA, ETR = 0.672
DCS	0% (<u><</u> 6.5% @ 95% cl)**	1.7% (<u><</u> 4.0% @ 95% ci) ***	1 / 4972 (1/3447 – 1/8928 ci)
Grade IV VGE	6.6% (≤16.3%@95% cl)	3.8% (≤12.4% @ 95% ci)	
4.0 HOUR (In-suit)			
N	28 wo LBA, TR = 1.60 0 / 4	with LBA, TR = 1.558	wo LBA, TR = 0.909
DCS	21% (≤38.0%@95% cl)	4.6% (<9.4% @ 95% ci)	1 / 1372 (1/960 – 1/2402 ci)
Grade IV VGE	39% (≤56.6%@95%cl)	9.9% (≤ 32.2% @ 95% ci)	
CAMPOUT (ISS)			
N	No direct ground tests or flight	with LBA, TR = 1.437	wo LBA, TR = 0.994
DCS		2.8% (<u><</u> 5.9% @ 95% ci)#	1 / 936 (1/656 – 1/1635 ci)#
Grade IV VGE		5.8% (≤19.0% @ 95% ci)#	
10.2 PSIA STAGED			
Ν	35 wo LBA, TR = 1.68 0 / 141	with LBA, TR = 1.507	wo LBA, TR = 1.287
DCS	23% (<37.5% @ 95% cl)	3.8% (≤7.6% @ 95% ci)	1 / 311 (1/217 – 1/549 ci)
Grade IV VGE	23% (≤37.5% @ 95% cl)	8.0% (≤ 26.0% @ 95% ci)	

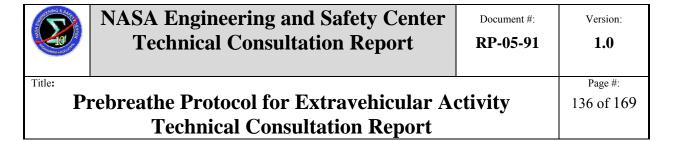
^{*}Includes operational margin, microgravity simulation (non ambulation), accounts for exercise with CEVIS protocol.

Note: GIV VGE prediction used 40 yo person in 6-hr simulated EVA, and only males are in the data for serious DCS.

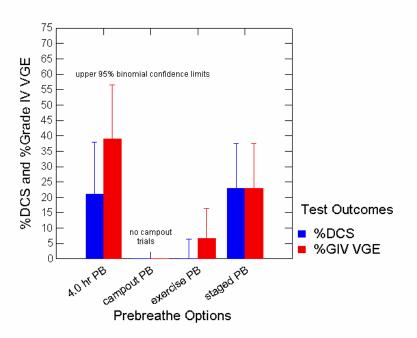
^{**}cl is upper 95% binomial confidence limit, based on observation of test result.

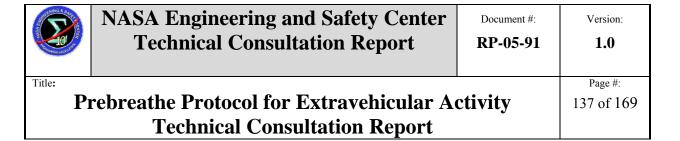
^{***}ci is the upper part of the 95% confidence interval, based on a statistical regression.

after an additional 10 min of prebreathe are added to the current 40 min in-suit prebreathe

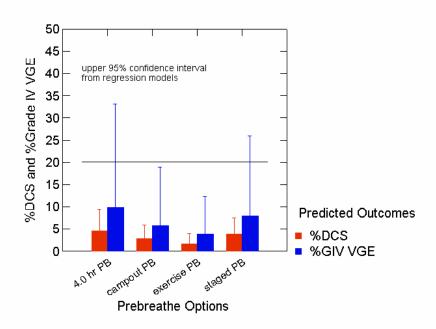


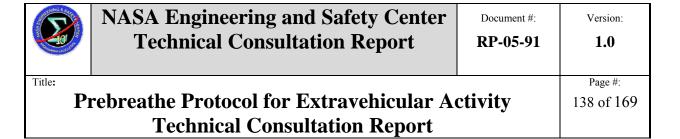
observed risk from ground trials



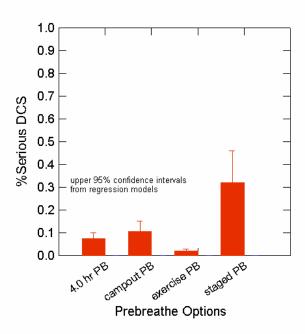


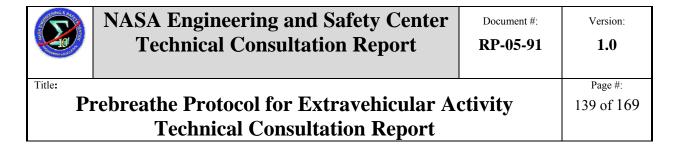
predicted risk accounting for flight factors



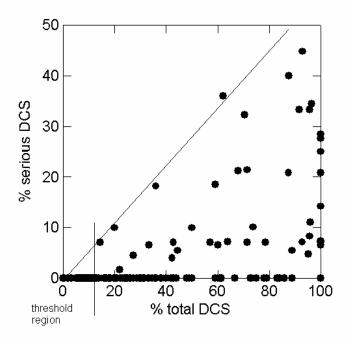


predicted risk accounting for flight factors





244 tests with 7692 exercising subjects



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Campout Prebreathe Protocol as Proposed 08/16/04

	PN2 360	PN2 180
1. 30 min 02 prebreathe		
2. 31 min O2- depress from 14.7 to 10.2 psi	10.314	9.1720
3. 8.0 hrs and 40 minutes at 10.2 psi / 26.5% 02	8.5345*	7.7258
4. 10 minute repress to 14.7 psia on O2 prebreathe		
5. 30 minute hygiene break while still on O2 prebre	eathe	
6. 31 min 02 - depress to 10.2 psia	7.4442	5.8780
7. 60 min suit donning at 10.2 psia while on 26.5%	O2 7.4503	6.2126
8. 17 min purge and leak check		
9. 40 mins-02 in-suit prebreathe	6.6761	4.9885
10. 10 min additional in-suit prebreathe		
11. 30 min depress to 4.3 psia on body	6.1812	4.2763
	TR360 = 1.4375	TR180 = 0.9945

^{*} This number is suspect since most of this time is spent sleeping.

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limitation of risk estimates for campout

- About 60% of campout time at 10.2 psia is spent sleeping compared to about 30% in shuttle staged protocol.
- We know that intense, short-duration exercise followed by mild, longer duration activity during prebreathe reduces the risk of DCS.
- It follows that prebreathe during sleep is less effective, and I have no defensible way to factor the contribution of sleep.
- We have not once measured VGE under actual EVA conditions in astronauts.

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interpretations of risk estimates

- Even in a list of "acceptable risks", there is a tendency to rank the risk.
- There is a tendency to select the lowest risk even when the absolute difference between two options is very small.
- The risk of Type I DCS does not imply anything about the operational impact of Type I DCS- 86% of Type I cases had symptom intensity stay the same or decrease as the test continued.
- Very low estimates of Type II DCS could very well mean no Type II DCS. But no one can guarantee no risk.

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concluding thoughts

- "Acceptance by analysis", "acceptance by similarity", or "in family" are less viable approaches today.
- Nothing is as informative as a validated test no model estimate can do better, only cheaper.
- But can you or should you validate every "minor" deviation??
- Validation of a new prebreathe protocol by a crew is a little novel in my experience – but we have provided a one-off option in STS-86, etc.
- All estimates seen here apply to groups of "similar" subjects – never to a particular astronaut.
- Accepting a particular risk MUST be balanced by the benefit of taking the risk – we evaluated the first part, and the operators have to evaluate the second part.



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THE EXERCISE PREBREATHE (PB) PROTOCOL, 4 HOUR IN-SUIT PB PROTOCOL, AND CAMPOUT PB PROTOCOL, ARE ALL ACCEPTABLE FOR USE ON ISS WITH VARYING DEGREES OF DCS RISK UNCERTAINTY. THE SELECTION OF A PB PROTOCOL FOR A GIVEN EVA WILL DEPEND ON THE INTEGRATED MISSION OBJECTIVES, DECOMPRESSION SICKNESS (DCS) RISK, CREW TIMELINE, AND OVERALL OPERATIONAL RISKS.

The PB protocol selected for a given EVA event should consider all the factors affecting risk to the crew and mission. Predicted risk of DCS, procedural risk due to timeline complexity or fatigue, and criticality of completing the EVA tasks within a specified timeframe are all factors that must be weighed.

The PB protocols are ranked according to their pedigree based on laboratory testing, on-orbit and suited vacuum chamber experience, and model predictions.

1. Exercise PB Protocol:

Rationale: The Exercise PB protocol meets the current DCS acceptance criteria, is the most rigorously laboratory tested, and the protocol with the lowest predicted risk of DCS. (This acceptable risk was defined in the NASA DCS Risk Definition & Contingency Plan, 1998, (total DCS ≤15% at 95% Confidence Limit (CL), ≤ 20% Grade 4 VGE at 95% CL, No Type II (Serious) DCS.)

2. 4 hr In-Suit PB Protocol:

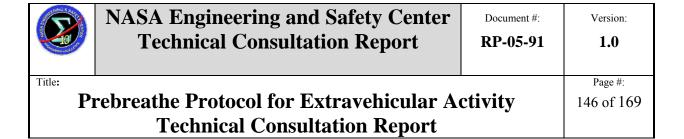
Rationale: The 4 Hr In-suit PB protocol has been extensively used on ground suited vacuum chamber exposures (> 300 exposures), with acceptable DCS risk (< 1.5% total DCS observed, no Type II). However, it has not undergone the same level of laboratory testing as the Exercise PB.

3. Campout PB Protocol:

Rationale: Model predictions and similarity to the Shuttle 10.2 psi staged-protocol show this to be an acceptable protocol, but with some increased risk, and greater uncertainty, compared to the Exercise PB Protocol. There is no direct laboratory testing, suited vacuum chamber, or direct on-orbit experience with the Campout protocol. However, this protocol was designed to be more conservative (as analytically determined) than the currently published shuttle 10.2 prebreathe protocol. (Ref. A13-103, EVA Prebreathe Protocol)

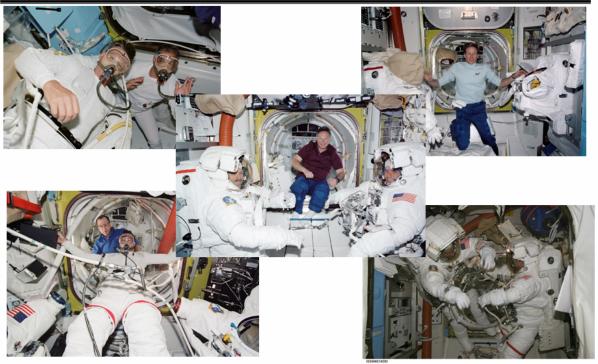
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Appendix H. "EVA Prebreathe Protocol Comparison: Operational Drivers"





EVA PREBREATHE PROTOCOL COMPARISON: OPERATIONAL DRIVERS



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EVA PB Protocol Options

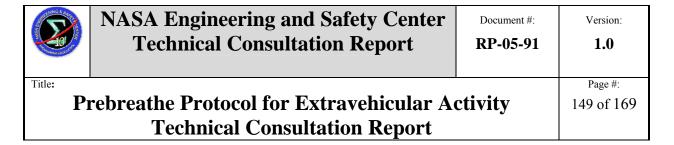
- For nominal EVAs, there are currently four prebreathe protocols certified for use:
 - 10.2 PSI Staged (Used only for shuttle based EVAs)
 - 4-Hour In-Suit (May be used on shuttle or station)
 - CEVIS Exercise (Used only for station based EVAs)
 - ISS Campout (Used only for station based EVAs)
- For contingency EVAs (EVAs which are required to effect the safety of the vehicle and crew):
 - The nominal EVA prebreathe protocols will be used if time allows.
 - If minimizing EVA preparation time is more critical to crew safety, then a minimum of 2.5 hours of unbroken prebreathe with > 95% O2 is recommended at a vehicle pressure above 12.5 psi/646 mmHg. (A min PB of 2.5 hours would reduce the estimated risk of incapacitating bends to <50% for an EVA up to 6 hours in duration. This recommended time is very approximate and should be extended if possible.)</p>
 - The Flight Surgeon will be consulted for a recommended prebreathe protocol for any contingency EVA.

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How do we choose a protocol?

- Our guidelines and options for prebreathe are defined in our Flight Rules
 - Vol A Shuttle Flight Rules; A13-103
 - Vol B ISS Flight Rules; B13-107
- When making a decision about using a prebreathe protocol, MOD considers the following factors:
 - Crew Safety
 - · DCS Prevention
 - · Fatigue factors
 - Crew Day Length (15.5 hrs ISS GGR&C; 16.0 hrs SCSC)
 - Vehicle and Suit Consumables Limitations
 - · Oxygen usage
 - · METOX/LiOH considerations
 - Operational issues
 - · Crew timeline, including overall day length
 - Length of the EVA
 - · Protocol complexity/Operational simplicity
 - Overall Mission objectives
 - Urgency of EVA (contingency/unscheduled EVA vs. planned/scheduled EVA)





Operational Flexibility

MOD would like the flexibility to choose from a variety of approved prebreathe protocols based on the needs of the mission and the EVA.



If you were planning a trip, you would choose a vehicle based on the needs of the excursion. In the same way, MOD like to be able to choose from a variety of prebreathe protocols based on the needs of the mission.

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Shuttle 10.2 PSI Staged Protocol Timeline

(Note: Pre-sleep time not shown)

		1:	:15		2:4	5 2:	53 4:08
60 min Mask PB	*12 HOURS AT 10.2 psi	POST SLEEP 75 min	EV.	A PREP 90 min		Purge	EMU PREBREATHE 75 min**
10.2 Dep				EMU Donning 55 min	Ck		
45 min before 12.5							

4:2	1	053	12:13
A/L Dep (15 min)	EVA PET = 6:30	Rep	POST EVA w/o H2O

^{*} If the EVA is scheduled within 36 hours of 10.2 Dep, this table may be used to calculate the Final EMU PB time.

INITIAL PREBREATHE TIME AT 10.2 PSI FINAL PREBREATHE 60 MINUTES 24 HOURS 40 MINUTES 60 MINUTES 20 HOURS 50 MINUTES 60 MINUTES 16 HOURS 60 MINUTES 60 MINUTES 12 HOURS 75 MINUTES

Note: Assume depress with AIRLK DEPRESS viv; 15 min. With 2 hours of Pre-sleep, STS Crew Day length = 14:17.

1 OR MORE DAYS PRIOR TO EVA DAY

- Mask Prebreathe (1 hour)
- Depress Shuttle Crew Cabin to 10.2 psi (12 hours minimum)

EVA DAY SUMMARY

- Post Sleep (1 hour 15 mins total)
- EVA Prep (1 hour 30 mins)
 - EVA Prep for Donning (30 mins)Suit Donning at 10.2 (1 hour)
- Suit Purge (8 mins)

EVA DAY SUMMARY (continued)

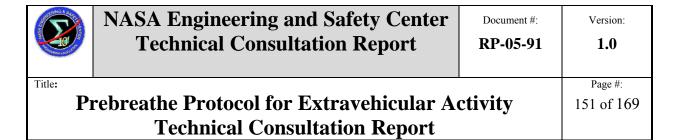
- •In-suit Prebreathe (40 to 75 mins depending on the time at 10.2 psi)
- •Crewlock Depress to vacuum (15 mins)
- •EVA tasks (6 hours 30 mins)
- •Airlock Repress (20 mins)
- •Post EVA without EMU H2O Recharge or METOX Regeneration (1
- •Pre Sleep (2 hours)

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^{**} The less time spent at 10.2, the longer the Final EMU Prebreathe time will be; thus, resulting in an overall longer crew day length. See chart.

^{***} If the EVA is scheduled later than 36 hours from 10.2 Dep, the initial PB may be eliminated and the final in-suit PB is 40 mins





4 hr In-suit Protocol Timeline

(Note: Pre-sleep time not shown)

1:15		2:45 2:	57		6:57
POST SLEEP 75 min	EVA PREP 90 min	Purge	EMU PREBREATHE	4 hours	
	EMU Donning 55 min	Ck			* Metox C/O
7:27				1357	15:17
C/L Depress (30 min)	*	EVA PET	= 6:30	Rep	POST EVA w/o H2O
* It is possible to perform MI	ETOX Change-Out (manned) to allow for	maximum E.V	A PET capability, Provided that Crew Day Length vio	ations can	he approved, we could

^{&#}x27;It is possible to perform METOX Change-Out (manned) to allow for maximum EVA PET capability. Provided that Crew Day Length violations can be approved, we could support a 6:30 EVA PET.

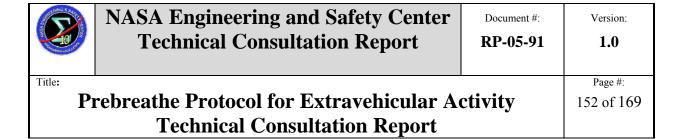
Note: Assume depress pump and EMERG MPEV & AL VAJ; 30 min C-Lk depress without built in hold at 5psi. With 2 hours of Pre-sleep, STS Crew Day length = 17:17.

EVA DAY SUMMARY

- •Post Sleep (1 hour 15 mins total)
- •EVA Prep (1 hour 30 mins)
 - -EVA Prep for Donning (30 mins)
 - -Suit Donning at 10.2 (1 hour)
- •Suit Purge (12 mins)
 - -Airlock Repress to 14.7
- •In-suit Prebreathe (4 hours)
- •Crewlock Depress to vacuum (30 mins)
- •EVA tasks (6 hours 30 mins)
- •Airlock Repress (20 mins)
- Post EVA without EMU H2O Recharge or METOX Regeneration (1 hour)
- •Pre Sleep (2 hours)

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CEVIS Exercise Protocol Timeline

(Note: Pre-sleep time not shown)

1:1	S	4	:05 4:	17		5:17	5:52
POST SLEEP 75 min	EVA PREP 170 min		Purge	EMU Piebi	reathe (60 min)	C/L Dep (35	min)
	Exercise PB/Prep for Donning - 80 min on mask total	EMU Donning 55 min Ck	Rep			•	
	50 min on mask prior to start of 10.2 depress 20 min Dep						
	EV1 ex* EV2 ex* Reqd 45 min mask P/B after exer						
	45 min reqd before below 11.8 psi						
				1222		139	42
	EVAPET = 6:30			Rep	POSTEV	A w/o H2O	

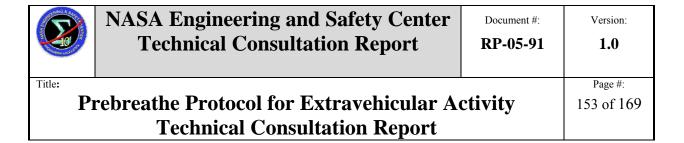
^{*} EV1 must start exercise within 10 min after PB initiate, EV2 must start exercise within 25 min after PB initiate to maintain 45 minute of mask time after exercise per FR.

Note: Assume depress pump and EMERG MPEV & AL VAJ; 40 min C-Lk depress with built in hold at 5psi PET = 25. With 2 hours of Pre-sleep, STS Crew Day length = 15:42.

EVA DAY SUMMARY

- Post Sleep (1 hour 15 mins)
- EVA Prep (Total of 2 hours 50 mins)
 - Mask Prebreathe (1 hour 20 mins)
 - 10 mins exercise for EV1
 - 10 mins exercise for EV2
 - 10.2 psi Airlock Depress (20 mins)
 - Mask Prebreathe Termination
 - Suit Donning at 10.2 (1 hour)
- Suit Purge (12 mins)
 - Airlock Repress to 14.7
- In-suit Prebreathe (60 mins)
- Crewlock Depress to vacuum (35 mins)
- EVA tasks (6 hours 30 mins)
- Airlock Repress (20 mins)
- Post EVA without EMU H2O Recharge or METOX Regeneration (1 hour)
- Pre Sleep (2 hours)
- 6/29/2005

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ISS Campout Protocol Timeline

(Note: Pre-sleep time not shown)

Night Before	EVA	L								
PRE SLEEP	3 hou	rs		Time @ 10.2 psi = 8 hours 40 mins (includes sleep)						
4	35		mask PB 10.2 Dep perfore 11.8	:45	3:1	5 3	:27		4:17	4:47
EVA Day	Н	YGIENE BRK	70 min	EVA PREP 90 min		Purge	EMU Prebreat	he (50 min)°	* C/L De	p (30 min)
		* 70 min mask	P/B	EM	IU Donning 55 min Ck	Rep				
	Rep		10.2 Depress							
POST SLEEP 35 min		POST SLEEP 40 min]				11	:17		1237
			EV.	A PET = 6:30				Rep P	OST EVA	w/o H2O

Note: Assume depress pump and EMERG MPEV & AL VAJ; 30 min C-Lk depress without built in hold at 5psi. With 2 hours of Pre-sleep, STS Crew Day length = 14:37.

NIGHT BEFORE EVA SUMMARY

- Pre Sleep (3 hours total)
- Mask Prebreathe (1 hour)
 - 10.2 psi Airlock Depress (20 mins)
- 10.2 psi Overnight Campout (8 hours 40 mins minimum) Suit Purge (12 mins)

EVA DAY SUMMARY

- Post Sleep (1 hour 15 mins total)
- Mask Prebreathe (1 hour 10 mins)
 - Airlock Repress
 - Hygiene Break/Post Sleep activities
 - 10.2 psi Airlock Depress
- Mask Prebreathe Termination

EVA DAY SUMMARY (continued)

- EVA Prep (1 hour 30 mins)
 - EVA Prep for Donning (30 mins)
 - Suit Donning at 10.2 (1 hour)
- - Airlock Repress to 14.7
- In-suit Prebreathe (50 mins)
- Crewlock Depress to vacuum (35 mins)
- EVA tasks (6 hours 30 mins)
- Airlock Repress (20 mins)
- Post EVA without EMU H2O Recharge or
 - METOX Regeneration (1 hour)
- Pre Sleep (2 hours)

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^{* 70} min mask P/B to begin only after 8hr 40 min at 10.2 psi per FR Assume 40 mins of HYGENE BREAK may be done in parallel with POST SLEEP.

^{**} In order to satisfy the accept criteria for ISS EVA protocols, an additional 10 minutes of in-suit prebreathe was added to the Campout protocol making the total in suit EMU Prebreathe for Campout = 50 mins.



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Comparison of EVA Prebreathe Protocols – SUMMARY TABLE

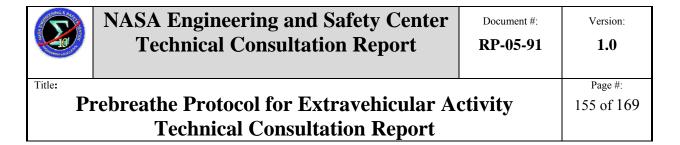
PROTOCOL COMPARISON	4-Hour In-Suit	CEVIS Exercise	Campout	Shuttle 10.2 Staged
Crew Time - EVA Prep and Prebreathe activities	5:42	4:02	4:42 (+ 8:40 min @ 10.2)	2:57 (+ 12:00 min @ 10.2)
Time In EMU	11:37	8:42	8:17	7:58 to 8:33 (depending on time @ 10.2)
EVA PET	6:30	6:30	6:30	6:30
STS Crew Day Length	17:17	15:42	14:37	14:17
STS Crew Day Length Violation (16:00 per SCSC) *	1:17	None (- :18)	None (-1:23)	None (-1:43)
ISS Crew Day Length	17:32	15:57	14:52	-
ISS Crew Day Length Violation (15:30 per GGR&C) *	2:02	:27	None (+:38)	-
Airlock Isolation	none	1:35	11:00	none
Mask Time (minimum)	none	1:20	2:10	1:00
Depress/Repress Cycles	1	2	3	2
Metox Cans Used per CM (EMU & AL Scrubbing)	1.5	1.5	2	1
Hatch-Hose Crossover	none	2	4	none
EVA PB 02 Usage**	~8.5 lbs	~22 lbs	~31 lbs	TBD

^{*} For STS crew Post Sleep duration is 1:15 and Pre Sleep duration is 2:00. Total crew day length is 16:00. [REF: SCSC document NSTS 37326 REV B].
For ISS crew, Post Sleep duration is 1:30 and Pre Sleep duration is 2:00. Total crew day length is 16:30. [REF: SSP 50261-01, REV A GENERIC GR &C (COLLATED MASTER - THRU DCN 016) 12/22/04.]

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^{**} Apprx. Values for total 02 for both CMs; Assumes N0 dry run 02 usage; In-Suit option assumes ~1.5 additional lbs 02 for the 2-min purge after METOX changeout.





Common EVA and Prebreathe Acronyms

- EVA Extravehicular Activity
- EMU Extravehicular Mobility Unit (or space suit)
- ISS International Space Station
- STS Shuttle Transportation System (or space shuttle)
- MOD Mission Operations Directorate
- PB Prebreathe
- DCS Decompression Sickness (or the "bends")
- CEVIS
- METOX Metal Oxide (this is the canister used on ISS to scrub carbon dioxide from the EMU)
- LiOH Lithium Hydroxide (this is the canister used on shuttle to scrub carbon dioxide from the EMU)
- GGR&C Generic Ground Rules and Constraints
- SCSC Shuttle Crew Scheduling Constraints
- PET Phase Elapsed Time
- A/L Airlock
- AL VAJ Airlock Vacuum Access Jumper
- C/L Crewlock (seen also as C-Lk)
- E/L Equipment Lock (seen also as E-Lk)
- PHA Portable Hose Assembly
- MCA Major Constituent Analyzer
- CSA-CP Compound Specific Analyzer Combustion Products
- MPEV Manual Pressure Equalization Valve

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Back Up Slides

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ISS EVA Prebreathe Flight Rule Change

CURRENT WORDING FOR B13-107 EVA PREBREATHE PROTOCOL [RC]

A. For all EVA's, prebreathing using the prebreathe hose Assembly (PHA) and the EMU will be accomplished using the exercise prebreathe protocol defined in paragraph A.1, unless the protocol defined in paragraph A.2 (10.2 psi/527 MMHg Campout) or A.3 (In-Suit) is required. @[060397-4734] @[032901-7470A] @[052302-5350A]

NEWLY PROPOSED WORDING FOR B13-107 EVA PREBREATHE PROTOCOL [RC]

A. The EXERCISE PREBREATHE (PB) PROTOCOL, 4 HOUR IN-SUIT PB PROTOCOL, and CAMPOUT PB PROTOCOL, are all acceptable for use on ISS with varying degrees of DCS risk uncertainty. The selection of a PB protocol for a given EVA will depend on the integrated mission objectives, decompression sickness (DCS) risk, crew timeline, and overall operation risks.

[060397-4734] [032901-7470A] [052302-5350A]

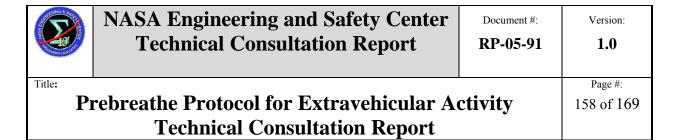
The PB protocol selected for a given EVA event should consider all the factors affecting risk to the crew and mission. Predicted risk of DCS, procedural risk due to timeline complexity or fatigue, and criticality of completing the EVA tasks within a specified timeframe are all factors that must be weighed.

The PB protocols are ranked according to their pedigree based on laboratory testing, on-orbit and suited vacuum chamber experience, and model predictions.

- 1. Exercise PB Protocol Rationale: The Exercise PB protocol meets the current DCS acceptance criteria, is the most rigorously laboratory tested, and the protocol with the lowest predicted risk of DCS. (This acceptable risk was defined in the NASA DCS Risk Definition & Contingency Plan, 1998, (total DCS < 15% at 95% Confidence Limit (CL), < 20% Grade 4 VGE at 95% CL, No Type II (Serious) DCS.)
- 2. 4 hr In-Suit PB Protocol Rationale: The 4 Hr In-suit PB protocol has been extensively used on ground suited vacuum chamber exposures (> 300 exposures), with acceptable DCS risk (< 1.5% total DCS observed, no Type II). However, it has not undergone the same level of laboratory testing as the Exercise PB.
- 3. Campout PB Protocol Rationale: Model predictions and similarity to the Shuttle 10.2 psi staged-protocol show this to be an acceptable protocol, but with some increased risk, and greater uncertainty, compared to the Exercise PB Protocol. There is no direct laboratory testing, suited vacuum chamber, or direct on-orbit experience with the Campout protocol. However, this protocol was designed to be more conservative (as analytically determined) than the currently published shuttle 10.2 prebreathe protocol. (Ref. A13-103, EVA Prebreathe Protocol)

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Prebreathe Hardware Comparison

CEVIS EX	KERCISE PROTOCOL	CAMPOUT PROTOCOL			
HARDWARE	FAILURE RESPONSE	HARDWARE	FAILURE RESPONSE		
CEVIS (including control box, PCM-CIA cards, shoes, etc.)	If available, Shuttle ergometer is permissible backup. All cycling shoes for CEVIS and Shuttle are interchangeable. CEVIS currently using IFM power supply for workload control due to control box failure.	EVA Prebreathe Hose Assembly Kits (PHA kits)	Kits include masks, hoses, relief vavles, and t- assemblies. For failure of any segment of kit, there are single redundancy to most items. Masks are identical to standard quick don masks and can be swapped out with ISS inventory. There is one 30ft spare segment of hose.		
CHeCS Heart Rate Monitor Chest Strap & Watch	If either fails, use alternate ISS CHeCS equipment	ISS Major Constituents Analyzer (MCA) for Overnight Campout	Used to monitor airlock atmosphere while isolated (i.e.: O2, CO2, N2). If failed, NO GO to continue.		
Black/Blue Theraband Exercise Tubing	Used for upper body resistance while cycling on CEVIS. A backup piece of tubing will nominally be installed on CEVIS. If both tubing fails, retrieve spare tubing on ISS.	ISS Major Constituents Analyzer (MCA) for 10.2 Ops	Used to monitor airlock atmosphere while isolated (i.e.: O2, CO2, N2). If failed, 2 CSA-CPs are required to continue prebreathe protocol. (Pending CSA-CP cert for O2 monitoring.)		
EVA Prebreathe Hose Assembly Kits (PHA kits)	Kits include masks, hoses, relief valves, and t- assemblies. For failure of any segment of kit, there are single redundancy to most items. Masks are identical to standard quick don masks and can be swapped out with ISS inventory. There is one 30ft spare segment of hose.	CHeCS CSA-CP for 10.2 Ops	Used for portable O2 monitoring while isolated in the Airlock. If the MCA is down, 2 units required. Otherwise, 1 unit is acceptable. (Pending CSA-CP cert for O2 monitoring.)		
ISS Major Constituents Analyzer (MCA) for 10.2 Ops	Used to monitor airlock atmosphere while isolated (i.e.: O2, CO2, N2). If failed, 2 CSA-CPs are required to continue prebreathe protocol. (Pending CSA-CP cert for O2 monitoring.)				
CHeCS CSA-CP for 10.2 Ops 6/29/2005	Used for portable O2 monitoring while isolated in the Airlock. If the MCA is down, 2 units required. Otherwise, 1 unit is acceptable. (Pending CSA-CP cert for O2 maniforing.)	s, Laura Moore 3-9139	Page 13		



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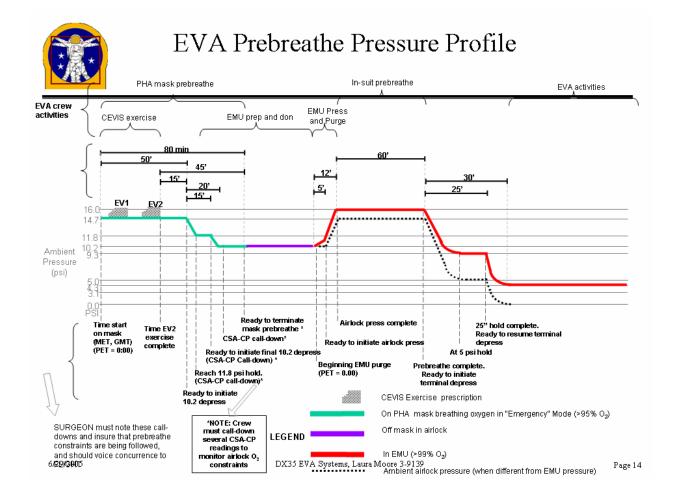
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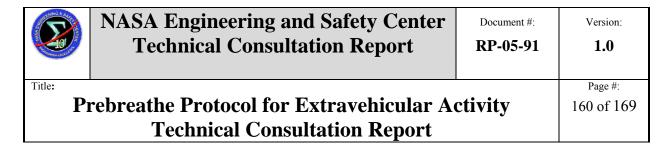
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EVA ISS Airlock Gas Usage

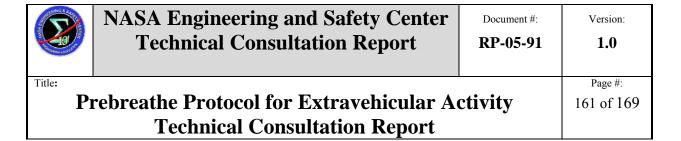
			EMU		Orlan
			Protocol		
Oxygen I	Jsage	Exercise (Ibm)	Campout Obm)	In-Suit Obm)	(Ibm)
Denitrogenization	Masks	10.79 (HP)2	14.27 (LP)3	0	0
	10.2 psia Ops	3.89 (LP)	7.78 (LP)	0	0
	Metabolic	0.613 (LP)	2.15 (LP)	0	0
EMU Support	Preb reathe	0.195 (HP)	0.13 (HP)	0.78 (HP)	0.35 (HP)
	Purge	3.512 (HP)	3.512 (HP)	3.512 (HP) 3.98* (HP)	1.87 (HP)
	Fill	2.82 (HP)	2.82 (HP)	2.82 (HP)	0.117 (HP) (Ingress- 10 minutes)
	Total (bm)	4.5 (LP) 17.32 (HP) 21.82 (Total)	24.2 (LP) 6.46 (HP) 30.66 (Total)	0 (LP) 7.11 (HP) 7.58* (HP) 7.11 (Total) 7.58* (Total)	0 (LP) 2.34 (HP) 2.34 (Total)
Air Losses					
	Air (Ibm)	4.28	4.28	4.28	4.28
	Dep ress Time (min)	10.5	10.5	10.5	10.5

- The indicators, LP (Low Pressure) and HP (High Pressure) indicate from which oxygen system the gas will be used.
- Assumes all oxygen comes from PHA ports.
 Assumes all oxygen comes from the PBA ports
 *Total purse with the optional additional 2 minu

Reference: 05Mar03; Daniel J. Leonard - ECLS

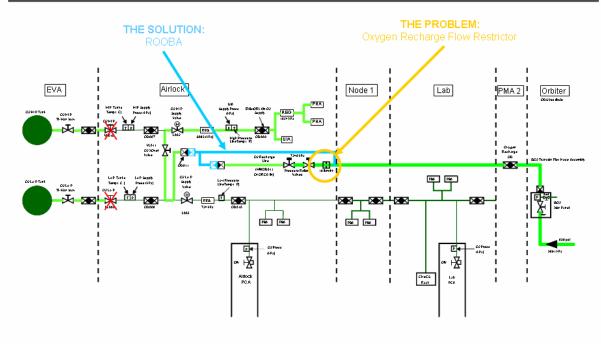
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$\begin{tabular}{ll} O2\ Config\ for\ EVA\ Prebreathe-\\ Post\ ROOBA\ (Recharge\ Oxygen\ Oriface\ Bypass\ Assembly)\ installation \end{tabular}$





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How often were we ahead/behind the timeline using the CEVIS Exercise Protocol?

FLIGHT	TIMELINED: READY FOR CREWLOCK DEPRESS (GMT)	ACTUAL: START OF CREWLOCK DEPRESS (GMT)	DIFFERENCE (Note: Due to the flight specific variations on Crewlock Depress times, for comparison, the times represented in this chart are when the crew started C/L Depress, NOT when they actually started the EVA.)
7A – EVA 3	2001/202/3:40	2001/202/03:29	AHEAD - 11 mins
8A – EVA 1	2002/101/14:15	2002/101/13:54	AHEAD - 21 mins
8A – EVA 2	2002/103/13:50	2002/103/13:24	AHEAD – 26 mins
8A – EVA 3	2002/104/13:50	2002/104/13:06	AHEAD - 44 mins
8A –EVA 4	2002/106/13:50	2002/106/13:46	AHEAD – 4 mins
9A – EVA 1	2002/283/14:00	2002/283/14:29	BEHIND – 29 mins
9A – EVA 2	2002/285/14:00	2002/285/13:48	AHEAD - 12 mins
9A – EVA 3	2002/287/14:00	2002/287/13:27	AHEAD - 33 mins
11A – EVA 1	2002/330/19:40	2002/330/19:03	AHEAD - 37 mins
11A - EVA 2	2002/332/18:40	2002/332/17:54	AHEAD – 46 mins
11A – EVA 3	2002/334/18:40	2002/334/18:44	BEHIND – 4mins
	AVERAGE		AHEAD ~ 18 mins

COMMENTS: In general, there are numerous reasons for a crew to run ahead or behind schedule. Some factors that allow a crew to get ahead are: crew wakes up early, EMU donning doesn't take the full 55 mins, crew gets more efficient after on-orbit experience. Some factors that could cause a crew to fall behind the timeline are: prebreathe hardware failures (CEVIS, PHA equipment, etc.), suit problems, breaks in prebreathe, delays in EVA sync points such as payload constraints, MT translation, or robotic arm movement.

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DCS (Decompression Sickness)

EVA Console Handbook, EVA/JSC-20597 REV C, PCN-1, Section 9.1

Decompression Sickness

DESCRIPTION

Decompression sickness is caused by a reduction in atmospheric pressure. DCS results when the pressure of dissolved gases in the tissues is greater than the ambient pressure, allowing inert gases, namely nitrogen, to evolve out of solution and form bubbles in the blood and tissues. These bubbles form microbubbles, which already exist throughout the body. Microbubbles can develop only in areas with pressures much lower than their surroundings, such as turbulent blood flow at points of vessel constriction or branching and muscles where shear forces are prevalent. Other low pressure areas may occur along the surfaces of cells or blood vessels where water does not adhere.

SYMPTOMS

There are two categories of DCS recognized by the medical community, type I and type II.

Type I - Joint pain

These symptoms are exhibited in roughly 90 percent of all DCS cases. In type I DCS, an abnormal sensation may be felt first in the arms and legs, followed by dull or throbbing pain in the joints, muscles, and bones. Type I DCS is commonly referred to as the "bends." Symptoms of type I DCS include joint pain, tingling, numbness, skin itching, and swelling. Pain may be made worse by physical activity. Joint pain may be relieved by applying direct pressure to the joint (as with a blood pressure cuff) or by raising the surrounding pressure, such as in a hyperbaric chamber.

Type II - Peripheral or central nervous system (CNS)

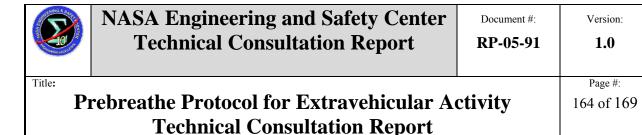
Incidents of type II DCS occur much less frequently than those of type I. •CNS Symptoms exhibited by aviators are usually traced to brain involvement. Divers tend to exhibit symptoms of spinal cord involvement. Brain involvement includes convulsive seizures, unconsciousness, stupor, collapse, nausea, vomiting, vertigo, headache, restlessness, speech impediments (aphasia), confusion, and personality changes. Spinal cord involvement includes paraplegia, monoplegia, muscular weakness, paralysis, muscle spasms, loss of bladder and rectal control, and altered reflexes.

Chokes

Symptoms can develop during exposure or several hours after. Symptoms are caused by a progressive obstruction of pulmonary capillaries by N2 bubbles carried to the lungs and result in reduced gas exchange and blood flow. They manifest as a dry nonproductive cough, labored shallow breathing, and chest pain upon inhalation. Chokes can lead to cyanosis, loss of consciousness, circulatory collapse, and even death.

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ISS GGR&C Reference

ISS Generic Ground Rules & Constraints, Part 2: Execute Planning; DRAFT (Rev A)
 Jul 2002 SSP 50261-02

3.1.3 Sleep Cycle 3.1.3.1 SLEEP DURATION

The nominal sleep period is 8.5 hours [TBR 3.1.1.1] and the minimum sleep period duration is 6.0 hours.

- a. Sleep period durations less than 8.5 hours [TBR 3.1.1.1] with a minimum of 6.0 hours may be scheduled for cases where vehicle arrival/departures require interruption of the nominal sleep period.
- b) For cases where the crew is scheduled to perform hazardous or demanding activities on the following day (e.g. EVA or EVR) a continuous 8.5 hour sleep period will be scheduled prior to the activity to allow the crew to receive at least 8.0 hours of sleep.

Rationale: If the sleep period is less than 6 hours, the crew will not receive enough rest. The agreed to sleep period of 8.5 hours [TBR 3.1.1.1] and resulting 15.5 hours awake time is based on Russian long duration flight experience on the Mir Space Station. This 8.5 hour [TBR 3.1.1.1] sleep duration also recognizes the fact that it takes some time to fall asleep. In a normal 24-hour day the crew should be awake 15.5 hours, followed by an 8.5 hour [TBR 3.1.1.1] sleep period.

The hazardous and demanding nature of EVA and EVR activities require crew members to be alert, therefore crew members should be scheduled for a continuous 8.5 hour [TBR 3.1.1.1] sleep period before these types of activities. Deviations to the 8.5 hour [TBR 3.1.1.1] sleep period may be required at the beginning of the crew's tour, the end of the crew's tour, joint operations, or to accommodate special mission requirements. Deviations which are not addressed in these ground rules and constraints will be addressed and agreed to as a waiver. Deviations to the 6 hour minimum will require a waiver and approval by the crew member and responsible ground medical personnel.

Source: New Rule. Operations Planning and Cargo Integration TIM#15, 11-22 September 1995, Protocol. Also derived from Shuttle Crew Scheduling Constraints (SCSC) NSTS 37326, July 16, 1998. RSA Operations and Utilization TIM#7, 14-25 April 1997, Protocol.

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STS SCSC Reference

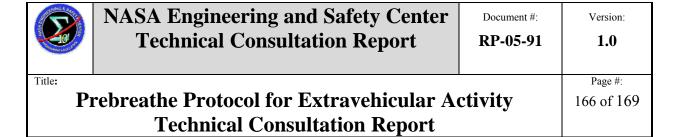
 Shuttle Crew Scheduling Constraints; Mission Operations Directorate Operations Division Flight Planning Branch; NSTS 37326, Revision B July 2004.

2.2.1 Sleep Durations

- a. A standard sleep period is 8 hours in duration and the minimum sleep period is
 6 hours. For flights 13 days or greater (per the Flight Requirements Document (FRD)), 8 hours is the minimum sleep period except as allowed in d. and e. below.
 - To maintain circadian rhythm, a crewmember should be awake for 16 hours and asleep for 8 hours. If the sleep period is less than 6 hours, the crew will not receive enough rest. For extended duration Shuttle missions, consistent, full-duration sleep periods are required to provide adequate crew rest.
- b. Consecutive sleep periods of less than 8 hours will not be scheduled. Scheduling consecutive sleep periods of less than 8 hours would fatigue the crew and disturb their circadian rhythm.
- c. A standard sleep period of 8 hours in duration will be scheduled the night before a critical day.
 If the sleep period is less than 8 hours, the crew will not receive enough rest to perform the critical FD activities.
- d. Sleep period duration must be equal to or greater than 8 hours on when the crew is sleep shifting more than 1 hour earlier. See section 2.2.2.1, for Sleep Cycle Shifting Constraints.
 - Shortened sleep periods combined with sleep shifting earlier can be very exhausting for the crew due to the changes in their circadian rhythm.
- e. On a single shift flight, the last on-orbit sleep period will be 8 hours in duration.
 The crew should be well rested for entry day activities.

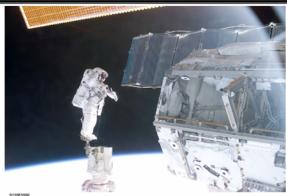
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EVA Pictures



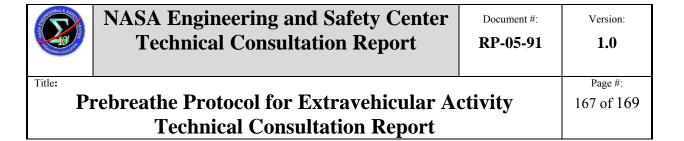






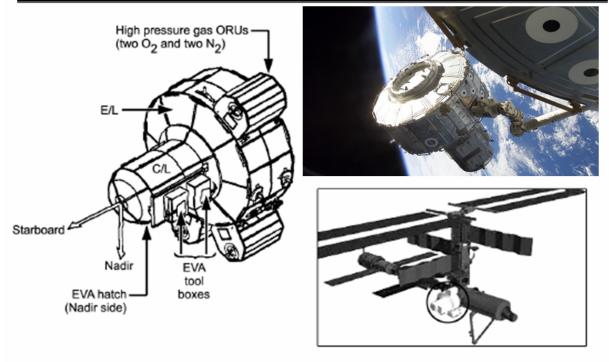
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ISS Airlock - "QUEST"



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Appendix I. List of Acronyms

CEVIS Cycle Ergometer with Vibration Isolation System

CL Confidence Limits CO₂ Carbon Dioxide

DCS Decompression Sickness

EVA Extravehicular Activity (Spacewalks)

IPT Integrated Product Team
ISS International Space Station

ITA Independent Technical Assessment

JSC Johnson Space Center KSC Kennedy Space Center

N₂ Nitrogen

NASA National Aeronautics and Space Administration

NESC NASA Engineering and Safety Center

NRB NESC Review Board

O₂ Oxygen PB Prebreathe

Psia Pounds Per Square Inch Absolute S&MA Safety and Mission Assurance SPRT Super Problem Resolution Team

TR Tissue Ratio

VGE Venous Gas Emboli VO₂ Oxygen Uptake

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Approval and Document Revision History

Original signed on file	8-28-05
NESC Director	Date
	6 6

Version	Description of Revision	Office of Primary Responsibility	Effective Date
1.0	Initial Release	Human Space Flight Operations SPRT	8-28-05